Applications for Modifications to HCPCS Level II Code Set
in the 2005-2006 Coding Cycle

The following list of applications, in order of request (tracking) number, provides a summary of each application submitted in the 2005-2006 HCPCS coding cycle for modifications to the HCPCS Level II code set. The information provided in each application summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government. Our intent in providing the summaries is to offer enough information about each application for the general public to formulate comments regarding individual applications. We look forward to your comments regarding the new summary format of the application listing, and regarding individual applications. Comments regarding specific applications may be submitted in writing or in person. Written comments can be e-mailed to: hcpcs@cms.hhs.gov
So that we can easily identify comments regarding applications, please state: COMMENT RE: #05.XXX (request number) in the subject line of your e-mail. Comments can also be provided in-person, orally or in writing, at an upcoming public meeting for HCPCS code requests. Agendas and registration information for the 2005 Public Meetings will be posted the first week of May 2005, on the official CMS HCPCS website at: www.cms.hhs.gov/medicare/hcpcs
We will consider all timely comments. Timely comments are those oral or written comments we receive before the close of the public meeting on the specific date the application that is the subject of your comment is discussed.

Request #05.01
Stuart Murray of Cubist Pharmaceuticals, Inc. submitted a request to establish a code for daptomycin for injection, trade name: Cubicin. According to the requester, Cubicin is used for the treatment of complicated skin structure infections caused by Gram-positive bacteria. This antibacterial agent is from a new class of antibiotics called cyclic lipopeptides. The active ingredient in Cubicin is daptomycin. Daptomycin causes rapid depolarization of the bacterial membrane, leading to cessation of bacterial DNA, RNA, and protein synthesis and resulting in bacterial cell death. Cubicin is administered intravenously. Recommended dosage is 4mg/kg administered over a 30-minute period by intravenous infusion in 0.9% sodium chloride injection once every 24 hours for 7 to 14 days. Cubicin is supplied in single-use vials containing 500mg daptomycin as a sterile, lyophilized powder.

Request #05.02
Bill Niland of Vapotherm, Inc. submitted a request to establish a code for a high flow humidification system, trade name: Vapotherm 2000h. According to the requester, The Vapotherm 2000h is the only device available that can comfortably and adequately deliver breathing gas flows of up to 40 liters per minute directly to a nasal cannula, or other small-tube respiratory interfaces, without a supplemental air source. This system consists of the base driver unit and a series of accessories for single patient use in the

patient's home. Vapotherm used membrane transfer technology to saturate a stream of air and/or oxygen to generate a high flow of warm and sterile vapor. High flow is indicated for numerous chronic lung diseases, acute respiratory insufficiency, apnea of prematurity, respiratory compromise where gas exchange in the respiratory tract needs improvement and where work of breathing needs to be reduced.

Request #05.03
Kevin Corcoran of Corcoran Consulting Group submitted a request to establish a code for an artificial cornea, trade name: AlphaCor™. According to the requester, Alphacor is an artificial cornea made of a biocompatible, flexible, hydrogel material similar to a soft contact lens. It contains central clear zone to provide refractive power and a peripheral skirt or rim made of an opaque porous sponge material which allows fibrovascular ingrowth for long term securing of the device into place. The device is available for those with no natural lens and for those with a lens in the eye.

Request #05.04
Lisa Burg of MED-TEC Inc. submitted a request to establish a code for implanted gold markers, trade name: Acculoc implanted gold localization markers. According to the requester, Acculoc implanted markers establish a permanent, accurate, internal reference system ensuring sub-millimeter localization accuracy at each delivery of radiation therapy dose. The markers show up distinctly on film, EPID, or CR images. These images are then brought into the Acculoc software, and 3D algorithms output the exact, sub-millimeter moves necessary to accurately position the patient, and the target, for high-precision radiotherapy dose delivery. This allows the radiation dose to be delivered to the tumor/target, sparing surrounding healthy tissue and critical structures.

Request #05.05A+B
Jessica Lurz of Dynasplint Systems, Inc. submitted a request to A) establish a modifier to distinguish between extension and flexion Dynasplint system, and B) establish a code for Dynasplint systems MCP extension and Dynasplint system MCP flexion. According to the requester, Dynasplint systems are joint stretch devices that provide a low-load prolonged-duration stretch for shortened connective tissue, thus relieving joint stiffness and regaining lost range of motion caused by injury, surgery, trauma or disease. Each unit is made of stainless steel that will withstand an extensive refurbishment process and soft interface material that comes in contact with the body. These MCP units are designed to be worn at rest or while sleeping for 8-10 hours to give patients several hours of therapy while sleeping. Each unit comes complete with a tensioning tool to either increase of decrease the force applied to the joint, according to the patient's comfort.

Request #05.09
Richard Weston of BlueSky Medical Group Inc. submitted a request to establish a code for powered suction pump, trade name: Versatile 1 Wound Vacuum System. According

to the requester, Versatile is a portable suction device that can be powered by an internal battery pack, wall current or 12 volt input via optional cigarette lighter adaptor. The pump can be used for removal of surgical fluids, tissues, gases, bodily fluids or infected materials during surgery or from a patients airway or respiratory support system. Versatile can also be used to create localized topical negative pressure when used with the Chariker-Jeter accessory kits to promote wound healing and drainage of fluids and infected materials from the wound into a disposable or reusable canister. Versatile consists of a medium sized housing that contains a vacuum pump and control system with a location for a fluid canister system. Accessories include a vehicle power adaptor and a Mobil stand. Versatile is indicated for promotion of wound healing or for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials from a patients airway or respiratory support system either during surgery or at the patients bedside.

Request #05.11
Marc Swartz of Dr. Len's Medical Products, LLC has submitted a request to establish a code for a bi-layer foam sleeve composed of a ¼" layer of foam with a 2lb deflection laminated to a second piece being ½" with a 1lb deflection. It is approximately 11" in length, looking like an elongated, tapered, oval. The bi-layer foam is sewn into a piece of fabric called Optimer® which is comprised of a blend of cotton, nylon, and two micro fibers called dri-release®, and FreshGuard®. The blended fabric is designed to keep the patient cool, dry by absorbing sweat, and odor free. The sleeve when applied to the site is designed to be able to pick up the body's pulse at the site. Product can be used for the prevention of injuries related to repetitive motion, and also used as a sports performance enhancement product.

Request #05.12
Marc Swartz of Dr. Len's Medical Products, LLC has submitted a request to establish a code for a wound care bandage system, Trade Name: Abrams Adjustable All-In-One Foam Wound Care Bandage System with 8% Silver Sodium Hydrogen Zirconium Phosphate. This product is designed to serve as a protective barrier over a wound or burn. The microbisan in the product is designed to keep the site free of infection for up to seven days, while the foam increases and enhances the circulation to the site of treatment, allowing wounds to heal more rapidly. It may also be used in the treatment of pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, and ischemic ulcers.

Request #05.13
Marc Swartz of Dr. Len's Medical Products, LLC has submitted a request to establish a code for a wound care bandage system, Trade Name: Abrams Adjustable All-In-One Foam Wound Care Bandage System. This product is designed to serve as a protective barrier over a wound or a burn, while providing enhancement of circulation to the site. The product is placed over a properly debrided wound in a manner that does not

compress the foam which, gently placed against the surface of the wound and skin, is able to pick up the microcirculation of the capillary bed.

Request #05.25
Linda Brown of In HomeCare Hair Shampooing Co, LLC submitted a request to establish a code for a hair shampooing chair, trade name: In Homecare Hair Shampooing Chair. According to the requester, In Homecare Hair Shampooing Chair is a shampooing chair that is specifically designed to provide a way to safely, conveniently, and effectively shampoo hair in the home, hospital, nursing homes, health care facilities, or when traveling. The main feature of the chair is the adjustable semi circular neck rest that is designed to support and stabilize the neck while shampooing the hair. The main purpose of the hair-shampooing chair is to protect the eyes, and ears, from suds and water during shampooing and rinsing by allowing water to freely flow away from the face. The main advantage of the chair is that the person would get a relaxing shampoo in the home, hospital, nursing home, or any other healthcare facility. The hair shampooing chair can be placed at the sink to shampoo hair, or placed into the bathtub to bathe the person and shampoo hair at the same time.

Request #05.26
Frank Joutras of Inverse Technology Corporation submitted a request to establish a code for a functional neuromuscular control device, trade name: Protonics. Requester claims that instruction to code at E1810 is inappropriate because the product is not being used for what E1810 was originally intended, Protonics is not a spring-loaded device or intended for non-functional use after surgery. Requester claims this is causing confusion to third party payers. Therefore requester is seeking a new E code. According to the requester, Protonics is an external limb component that is added to, or part of an orthosis. This device is used only while the patient is functioning to control neuromuscular activation of certain muscle groups during motion allowing the device to influence joint kinematics and contact areas associated with the pelvis, femur and patella resulting in increased function and decreased pain during activities. Protonics uses a patented and unique form of functional resistance to influence certain neuromuscular activity only while the patient is walking or performing functional movements. Usage of the device needed on a daily basis is patient dependent, but most patients will need to use the device extensively over the first few months, and then periodically based on their activity level.

Request #05.27
Stephen McGill of Novo Nordisk has submitted a request to change Q0187 to a J code and to change the dosage from “per 1.2 mg” to “per microgram”. Q0187 currently reads: FACTOR VII A (COAGULATION FACTOR, RECOMBINANT) PER 1.2MG. The applicant has requested this change to a J code to be consistent with the other clotting factors used by hemophilia patients. In addition, although the drug is packaged in 1.2 mg. vials, it is administered in microgram doses. According to the requester, NovoSeven Coagulation Factor VIIa (recombinant) is indicated for treatment of bleeding episodes in

hemophilia A or B patients with inhibitors to Factor VIII or Factor IX and is the only approved recombinant FVIIa for effective, reliable treatment of bleeding episodes in this patient population. It is intended for intravenous bolus administration. The recommended dose of NovoSeven is 90ug/kg given every two hours until hemostasis is achieved or until the treatment has been judged to be adequate.

Request #05.28A-E
Lisa Saake, of Tyco Healthcare/Mallinckrodt, has submitted a request modify the coding for low osmolar contrast drugs for 2006. She has presented two options, which are as follows:
Option 1: Revise A4644 to include a quantity of contrast administered. For example, A4644 Low osmolar contrast 100-199 concentration, per mL. Delete A4645 and replace it with a series of codes that more accurately describes the products on the market today. For example, AXXXX Low osmolar contrast 240 concentration, per mL. Delete A4646 and replace it with a series of codes that more accurately describes the products on the market today. For example, AXXXX Low osmolar contrast 300 concentration, per mL.
Option 2: Delete codes A4644-A4646 and create new codes for low osmolar agents based on each manufacturer's chemical ingredient and concentration of iodine, as below:

Optiray 160– Indicated for intra-arterial digital subtraction angiography. Ioversol injection 34% (Optiray 160) is available in 50 ml and 100 ml glass bottles. It opacifies vessels in the path of the flow of the contrast medium permitting radiographic visualization of the internal structures for diagnostic or therapeutic purposes.

Optiray 240 – Indicated for angiography and venography as well as contrast enhanced computed tomographic imaging of the head and body. It is also indicated for intravenous excretory urography. Ioversol 51% (Optiray 240) is available in 50 mL, 100 mL, 150 mL, and 250 mL glass bottles, 50 mL hand-held syringes, and 125 mL power injector syringes.

Optiray 300 - Indicated for cerebral angiography and peripheral arteriography, as well as contrast enhanced computer tomographic imaging of the head and the body, venography and intravenous excretory urography. Ioversal Injection 64% (Optiray 300) is supplied in 50 mL, 100 mL, 150 mL, and 200 mL glass bottles, 50 mL hand held syringes, 100 mL power injector syringe, and 500 mL Pharmacy bulk pack.

Optiray 320 - Indicated in adults for angiography throughout the cardiovascular system. It enhances computed tomographic imaging through augmentation of radiographic efficiency for diagnostic purposes or therapeutic patient management. Ioversal Injection 68% is supplied in 20 mL, 30 mL, 50 mL, 75 mL, 100 mL, 200 mL glass bottles, 30 mL and 50 mL hand held syringes, 50 mL, 75 mL, 100 mL and 125 mL power injector syringes, and 250 mL pharmacy bulk packs.

Optiray 350– Indicated in adults for peripheral and coronary arteriography and left ventriculography. It is also indicated for contrast enhanced computer tomographic

imaging of the head and the body, intravenous excretory urography, intravenous digital subtraction angiography and venography. It is indicated in children for angiocardiography. Ioversol Injection 74% (Optiray 350) is available in 50 mL, 75 mL, 100 mL, 150 mL, and 200 mL glass bottles, 30 mL and 50 mL hand held syringes, 50 mL, 75 mL, 100 mL, and 125 mL power injector syringes, and 250 mL and 500 mL pharmacy bulk packs.

Request #05.29
Lisa Saake of Tyco Healthcare/Mallinckrodt has submitted a request to:
Option 1: Revise code A4644 to include a quantity of contrast administered, delete A4645 and A4646 and replace them with a series of codes that more accurately describe the products on the market today, or
Option 2: Delete codes A4644-A4646 and create new codes for low osmolar agents based on each manufacturer's chemical ingredient and concentration of iodine.
This request would also include the establishment of a code for Ioxaglate Meglumine 39.3% and Ioxaglate Sodium 19.6% Injection USP, Trade Name: Hexabrix.

According to the requester, Hexabrix opacifies vessels in the path of the flow of contrast medium permitting readiographic visualization of the internal structures for diagnostic or therapeutic purposes. It enhances computed tomographic imaging through augmentation of radiographic efficiency for diagnostic purposes or therapeutic patient management.

Request #05.30
Lisa Saake of Tyco Healthcare/Mallinckrodt has submitted a request to discontinue A4643 and A4647 and establish new codes that more accurately describe magnetic resonance contrast agents based on the chemical ingredient. In addition, the requestor would like to add a quantity description, per mL, to the code. Specifically, the requester suggests the establishment of a new code and recommended the following language: "GADOVERSETAMIDE INJECTION, PER ML", Trade Name: OptiMARK®.
According to the requester, OptiMARK® is a paramagnetic agent that develops in a magnetic moment when placed in a magnetic field. The relatively large magnetic moment can enhance the relaxation rates of water protons in its vicinity leading to an increase in signal intensity, (brightness) of tissue. OptiMARK® is available in 5, 10, 15 and 20mL glass vials and 10, 15, 20, and 30mL plastic syringes.

Request #05.31
Mike Brown of Biogen Idec, Inc. has submitted a request to modify HCPCS code A9523 (Supply of radiopharmaceutical therapeutic imaging agent, Yttrium 90 Ibritumomab Tiuxetan, per mCi) to read "per dose" rather than "per mCi". According to the requester, Zevalin is indicated for the treatment of patients with relapsed or refractory low-grade, follicular or CD20+ transformed B-cell non-Hodgkins lymphoma, and for the treatment of patients with RITUXAN-refractory follicular non-Hodgkins lymphoma. It is prepared

by a radiopharmacist in a patient-specific single use dose, who then sends the final product to the licensed provider facility in a pre-filled syringe for patient administration.

Request #05.32
Mike Brown of Biogen Idec, Inc. has submitted a request to modify HCPCS code A9522 (Supply of radiopharmaceutical diagnostic imaging agent, Indium-111 Ibritumomab Tiuxetan, per mCi) to read "per dose" rather than "per mCi". According to the requester, Zevalin is indicated for the treatment of patients with relapsed or refractory low-grade, follicular or CD20+ transformed B-cell non-Hodgkins lymphoma, and for the treatment of patients with RITUXAN-refractory follicular non-Hodgkin's lymphoma. ^{111}Indium Zevalin is prepared using the ^{111}Indium Zevalin kit, which contains all of the non-radioactive ingredients necessary to produce a single dose of ^{111}Indium Zevalin. The radiopharmacist prepares a single patient-specific dose, and then sends the final product to the licensed provider facility in a pre-filled syringe for patient administration.

Request #05.33
Lisa Saake of Tyco Healthcare/Mallinckrodt has submitted a request to convert C1093 SUPPLY OF RADIOPHARMACEUTICAL DIAGNOSTIC IMAGING AGENT, TECHNETIUM TC 99M FANOLESOMAB, PER DOSE (10 - 20 mCi) to an A or J code. The language suggested by the requester is AXXXX Supply of Radiopharmaceutical diagnostic imaging agent, Technetium Tc99m fanolesomab per dose (10-20 mCi). The product that is the subject of this request, NeutroSpec™, according to the requester, is a Technetium labeled antibody that is injected directly into a patient. It is an intravenously administered diagnostic imaging agent that binds in vivo, with high affinity and specificity to white blood cells and myeloid precursors. It is administered in a single intravenous dose of 10-20 mCi for diagnostic nuclear imaging procedures.

Request #05.34
David I. Bell of Grifols Biologicals, Inc. has submitted a request to establish a code for an immune globulin intravenous (human) liquid, pasteurized, Trade Name: Flebogamma 5%, used to replace immunoglobulins in patients who have congenital or hereditary lack or deficiency of IgG. According to the requester, Flebogamma 5% is a liquid pasteurized intravenous immunoglobulin solution obtained from the plasma of normal U.S. donors. According to the requester, Flebogamma 5% is the only sorbitol stabilized immunoglobulin product available in the marketplace. The requester claims that it is manufactured using a proprietary process utilizing a stabilizer and other components which give rise to a significantly different risk profiles, including incidence of renal failure, stroke and myocardial infarction, by virtue of using sorbitol as a stabilizing agent which has not been associated with renal damage due to hyper-osmotic overload, or stroke or M.I. due to increased blood viscosity. Flebogamma is administered intravenously and dosed by weight. Most patients receive monthly infusions, although some require infusions on a more frequent basis. The usual dose of Flebogamma 5% for

replacement therapy in primary humoral immunodeficiency diseases is 300 to 600 mg/kg body weight administered every 3 to 4 weeks. Doses may be adjusted over time to achieve the desired trough IgG levels and clinical response. It is supplied in single dose vials containing 0.5, 2.5, 5 or 10 gram vials of IgG as a 5% liquid solution. The requester claims that existing codes J1563 and J1564 do not allow for accurate billing according to dose by weight and claims that Medicare reimbursement is less than the cost of the product.

Request # 05.35

Mark Reese of Ortho Biotech Products has submitted a request to establish a code for high molecular weight hyaluronan, Trade Name: ORTHOVISC. According to the requester, ORTHOVISC is a high molecular weight, ultra-pure natural hyaluronan dissolved in physiological saline drug that is supplied in a single use syringe and is intended for one time use only. ORTHOVISC is used in the treatment of pain due to osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics (e.g. acetaminophen). The treatment course consists of three or four intra-anticular injections administered weekly. The requester claims that combined analysis of two large clinical studies demonstrate significantly larger proportion of ORTHOVISC-treated patients achieving a 40% or 50% improvement in WOMAC pain score (Western Ontario McMaster) compared to controls. Clinical safety and efficacy studies have demonstrated symptomatic relief for 27 weeks.

Request #05.36

Deanna Darlington of Pharmion Corporation has submitted a request to establish a code for azacitidine for injectable suspension, Trade Name: Vidaza ™. According to the requester, Vidaza™ contains azacitidine, a pyrimidine nucleoside analog of cytidine. It is classified as an antimetabolite by the FDA and is the only treatment commercially available to treat the five sub-types of Myelodysplastic Syndrome. It is believed to exert its antineoplastic effects primarily through hypomethylation of newly synthesized DNA. Methylation is an epigenetic mechanism by which gene expression may be switched off in certain cell types. Patterns of methylation vary within tissue and cell type. It is supplied in a sterile form for reconstitution and subcutaneous injection only. Vials of Vidaza contain 100mg. Of azacitidine and 100mg. Mannitol as a sterile lyophilized powder. The recommended starting dose of Vidaza is 75mg/m2 subcutaneously, daily for seven days, every four weeks. It may be increased to 100mg/m2 if no beneficial effect is seen after two treatment cycles and if no toxicity other than nausea and vomiting has occurred. It is recommended that patients be treated for a minimum of 4 cycles, although complete or partial response may require more than 4 treatment cycles. It may be continued as long as the patient continues to benefit.

Request #05.37

Marie DiFiore of Bracco Diagnostics has submitted a request to change existing code Q3000 " SUPPLY OF RADIOPHARMACEUTICAL DIAGNOSTIC IMAGING AGENT, RUBIDIUM RB-82, PER DOSE" to an "A" code for Rubidium Chloride Rb-82, Trade Name: CardioGen-82®. Proposed code A95XX with exact same language as Q3000. According to the requester, CardioGen-82 is a generator containing accelerator produced strontium Sr-82 absorbed on stannic oxide in a lead-shielded column and provides a means for obtaining sterile nonpyrogenic solutions of rubidium chloride Rb-82 injection. The injection is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected myocardial infarction. CardioGen-82 (Rubidium Rb 82 Generator) must be used with an infusion system specifically labeled for use with the generator and capable of accurate measurement and delivery of doses of rubidium chloride Rb 82 injection not to exceed a single dose of 2220 MBq (60 mCi) and a cumulative dose of 4440 MBq (120 mCi).

Request #05.38

Marie DiFiore of Bracco Diagnostics has submitted a request to establish a code for Sincalide lyophilized powder for injection, Trade Name: Kinevac®. The applicant proposed the following code language: JXXXX – Injection, Sincalide USP, per 5 mcg. According to the requester, Sincalide is labeled to stimulate contraction of the gallbladder prior to cholecystography with contrast media, ultrasonography, or duodenal aspiration of bile. Sincalide is also labeled to stimulate pancreatic secretions in conjunction with secretin prior to duodenal aspiration and to speed the gastrointestinal transit of barium meals. Sincalide is a synthetic octapeptide, pharmacologically similar to cholecystokinin. Both agents increase intestinal motility and cause gallbladder contractions, reducing gallbladder size and causing bile evacuation. Sincalide also stimulates the acinar cells of the pancreas and can potentiate the pancreatic effects of secretin.

Request #05.39

Juliana Reed of Baxter Healthcare submitted a request to establish a code for frozen premix penicillin G potassium for injection. According to the requester, Penicillin G Potassium in Plastic Container, herein referred to as Frozen Premix Penicillin G Potassium Injection, USP (equivalent to 1, 2 or 3 million units of penicillin G), is a 50mL, premix, iso-osmotic, sterile, nonpyrogenic, frozen solution for intravenous administration. It is a non-antipseudomonal antibiotic used to treat infections caused by bacteria. It works by killing the bacteria or preventing their growth. Dextrose, USP has been added to the dosages to adjust osmolality (approx. 2g, 1.2g, and 350mg as dextrose hydrous, respectively.) Sodium citrate, USP has been added as a buffer. The pH has been adjusted with hydrochloric acid and may have been adjusted with sodium hydroxide. The pH is 6.5 (5.5 to 8.0). The solution is contained in a single dose GALAXY container. This GALAXY container is fabricated from specially designed multilayer plastic (PL 2040 Plastic).

Request #05.40

Juliana Reed of Baxter Healthcare submitted a request to establish a code for frozen premix vancomycin injection U.S.P. According to the requester, Vancocin® HCL in Plastic Container, herein referred to as Frozen Premix Vancomycin Injection, USP, is frozen iso-osmotic, sterile, nonpyrogenic premixed 100 mL or 200 mL solution containing 500mg or 1 g Vancomycin, USP respectively as Vancomycin Injection, USP. It is a tricyclic glycopeptide antibiotic derived from Amycolatopsis orientalis. It is used to treat infections in many different parts of the body. It is sometimes given with other antibiotics. Vancomycin given by injection is used mainly for serious infections for which other medicines may not work. The drug product is an antibiotic used primarily to treat susceptible strains of methicillin-resistant staphylococci.

Request # 05.41

Deborah Walton of Valera Pharmaceuticals, Inc., has submitted a request to establish a code J92xx for histrelin implant, Trade Name: Vantas. According to the requester, Vantas is a sterile, nonbiodegradable, diffusion-controlled, reservoir drug delivery system designed to deliver histrelin continuously for 12 months upon subcutaneous implantation. The Vantas implant contains 50mg of histrelin acetate. Histrelin acetate is a synthetic nonapeptide analogue of the naturally occurring gonadotropin releasing hormone (GnRH) or luteinizing hormone releasing hormone (LH-RH). The sterile Vantas implantation device (provided in the implantation kit shipped with the implant) is used to insert the implant subcutaneously in the inner aspect of the upper arm. After 12 months, the implant must be removed, at which time another may be inserted to continue therapy for an additional 12 months.

Request #05.42

Barbara Ossias, of GE Healthcare, has submitted request establish separate codes for Technetium-99m Exametazime, (Ceretec™). According to the requester, Ceretec can be used as an adjunct in the detection of altered regional cerebral perfusion in stroke. Without methylene blue stabilization, it is indicated for leukocyte labeled scintigraphy as an adjunct in the localization of intra-abdominal infection and inflammatory bowel disease. Currently, A9521 (Supply of radiopharmaceutical diagnostic imaging agent, technetium Tc 99m exametazine, per dose) is used to denote Ceretec for both infection imaging and brain imaging, despite the variants in how the product is administered for each utilization. The Ceretec kit is supplied as a kit containing five vials with different clinical utilizations. Each vial of Ceretec contains a predispensed sterile, non-pyrogenic, lyophilized mixture of 0.5mg Exametazime. In addition, each package contains five 1ml vials of Methylene Blue Injection USP and five 4.5ml vials of 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP in 0.9% Sodium Chloride Injection USP.

Request #05.43

Tamar Thompson, of Amersham Health Inc., d.b.a. GE Healthcare, has submitted a request to establish a unique code for iso-osmolar contrast materials, including Visipaque, and other future IOCM products. According to the requester, Visipaque is a dimeric, nonionic, water soluble, iodinated, radiographic contrast medium that is isosmolar to blood at all clinically relevant concentrations. It is administered via intravascular administration and delivers twice the iodine of other contrast agents per molecule with less than half of the osmality of conventional low osmolar agents, and significantly less than high osmolar agents providing advantages, according to recent literature, for high risk patients. It is used to visualize organs. Contrast mediums work by blocking x-rays, thus increasing the visual contrast of soft tissues in the body.

Request #05.44
Jonathan Williams, M.H.A., of Lash Group Healthcare Consultants, has submitted a request to establish a code for pegaptanib sodium injection, Trade Name: Macugen®. The language suggested by the applicant is JXXXX Pegaptanib sodium injection, 0.3 mg. According to the requester, Macugen is used in the treatment of neovascular (wet) age-related macular degeneration (AMD). Pegaptanib is a selective vascular endothelial growth factor (VEGF) antagonist. VEGF is a secreted protein that selectively binds and activates its receptors located primarily on the surface of vascular endothelial cells. It induced angiogenesis and increases vascular permeability and inflammation, all of which are thought to contribute to the progression of the neovascular form of age-related macular degeneration. It is supplied in a single-dose, pre-filled syringe and is formulated as a 3.47 mg/mL solution to deliver a dose of 0.3 mg pegaptanib in a nominal volume of 90µL. It is administered via an intravitreal injection.

Request #05.45
Jay Schafer of Berlex Laboratories submitted a request to establish a unique code for Iopromide, Trade Name: Ultravist®. According to the requester, Ultravist® (Iopromide) is a nonionic, water soluble, tri-iodinated x-ray contrast agent for intravascular administration. Intravascular injection of iopromide opacifies those vessels in the path of flow of the contrast agent, permitting radiographic visualization of the internal structures until hemodilution occurs. Ultravist® (Iopromide) is injected either directly into a vein or through a catheter into an artery prior to x-ray imaging procedure. Injection for any patient scheduled to undergo an imaging procedure that requires the use of a contrast agent (CAT scan, IVP, arteriogram, angiogram, cardiac cath procedure, etc). According to the applicant, existing codes A4644, A4645 and A4646 describing low osmolar contrast agents “do not effectively distinguish drugs which are separate chemical entities”.

Request #05.46
Elizabeth Spurgin of DEY, L.P. has submitted a request to modify the verbiage of code J7616 ALBUTEROL, UP TO 5 MG AND IPRATROPIUM BROMIDE UP TO 1 MG,

COMPOUNDED INHALATION SOLUTION, ADMINISTERED THROUGH DME to instead read ALBUTEROL, UP TO 2.5 MG AND IPRATROPIUM BROMIDE UP TO 0.5 MG, IN PREMEASURED AND PREMIXED VIAL, INHALATION SOLUTION, ADMINISTERED THROUGH DME to specifically exclude inhalants compounded by a pharmacy, and to describe a single dose. The issue involves DuoNeb® Inhalation Solution, which is a dual-therapy nebulizer solution for the treatment of bronchospasm associated with COPD for patients requiring more than one bronchodilator. DuoNeb combines two proven respiratory solutions in one premixed, premeasured, 3mL unit dose vial for nebulization: albuterol sulfate and ipratropium bromide. It is supplied in a 3mL sterile solution for nebulization in sterile low-density polyethylene unit-dose vials, packaged as either single vial or cards of 5 vials in foil packages.

Request #05.47
Elizabeth Spurgin of DEY, L.P. has submitted a request to discontinue code J7617. The requestor believes that J7617 does not describe any item or service that is currently on the market, and the existence of this code could encourage inappropriate pharmacy compounding.

Request #05.48
James Coccia of Genzyme Corporation submitted a request to establish a code for clofarabine, Trade Name: CLOLAR™. According to the requester, CLOLAR™ is indicated for the treatment of pediatric patients 1 to 21 years old with refractory or relapsed acute leukemia. Clofarabine is sequentially metabolized intracellularly to the 5' –monophosphate metabolite by deoxycytidine kinase and mono- and di-phosphokinases to the active 5' –triphosphate metabolite. Conversion of the monophosphate to the diphosphate is the rate-limiting step resulting in cellular accumulation of both clofarabine mono- and tri-phosphate. Clofarabine has high affinity for the activating phosphorylating enzyme, deoxycytidine kinase, equal to or grater than that of the natural substrate, deoxycytidine. CLOLAR™ has demonstrated anti-cancer activity through inhibition of DNA synthesis and repair, introduction of apoptosis, and possibly through other mechanisms.

Request #05.49
Jay Schafer of Berlex Laboratories submitted a request to establish a code for gadopentetate dimeglumine, trade name: Magnevist®. According to the requester, Gadopentetate dimeglumine is a paramagnetic extracellular contrast drug for Magnetic Resonance Imaging (MRI). Gadopentetate dimeglumine is used to detect and characterize lesions with abnormal vascularity. Gadopentetate dimeglumine gives radiologists the ability to distinguish normal and abnormal tissues in MR exams. This impacts the confidence and accuracy of the diagnosis as well as the speed of the MRI exam. Gadopentetate dimeglumine is injected either directly into a vein or through a catheter into an artery prior to magnetic imaging procedure. The recommended dosage of

gadopentetate dimeglumine is 0.2 ml/kg (0.1 mmol/kg) administered intravenously at a rate not to exceed 10mL per 15 seconds.

Request #05.50
John Warner of Guerbet LLC has submitted a request to establish 2 codes for Oxilan (Ioxilan) Injection: one for 300mgI/ml; and one for 350 mgI/ml. According to the requester, Oxilan Injection is a non-toxic, iodinated, low osmolality contrast medium used for contrast enhancement during x-ray and CT examination procedures. It provides contrast needed to adequately image vasculature, internal organs, etc. due to atoms of iodine carried by the molecule, which are optically dense, thereby giving an image with different visual gradations. It is supplied as Oxilan 300mg/mL and Oxilan 350 mg/mL.

Request #05.51
Tom Mitro of ISTA Pharmaceuticals has submitted a request to establish a code for Ovine Hyaluronidase, Trade Name: Vitrase®. According to the requester, Vitrase is derived from ovine testes from New Zealand, a non-bovine spongiform encephalopathy (BSE) source. As a spreading agent, it has found medical applications in ophthalmic anesthesia, subcutaneous urography, hypodermoclysis, and the treatment of certain malignancies. It is a spreading or diffusing substance, which modifies the permeability of connective tissue through the hydrolysis of hyaluronic acid. Hyaluronidase hydrolyzes hyaluronic acid by splitting the glucosaminidic bond between C1of the glucosamine moiety and C4 of glucuronic acid. This temporarily decreases the viscosity of the cellular cement and promotes diffusion of injected fluids or of localized transudates or exudates, thus facilitating their absorption. Dosages range from 55 IU in 50 µL to 200,000 IU. It is commonly injected, including subcutaneous, peribulbar, Sub Tenons, retrobulbar and intravitreal. For certain malignancies, intravenous use may be utilized. Vitrase is supplied in sterile 6200 units of lyophilized ovine hyaluronidase non-preserved in a single use 5ml vial, one 1 mL sterile polycarbonate syringe and one 5 µm sterile needle. It is also supplied as 200 USP units/mL of ovine hyaluronidase non-preserved in a single use 2mL glass vial.

Request #05.52
Nick Poulios, PhD of Elan Pharmaceuticals, Inc. has submitted a request to establish a code for Natalizumab, Trade Name: Tysabri®. Applicant requests the following code language: Jxxxx INJECTION, NATALIZUMAB FOR INTRAVENOUS INFUSION, 300MG, to differentiate Tysabri from other products. According to the requester, Tysabri, the only humanized monoclonal antibody approved for the treatment of multiple sclerosis (MS), inhibits adhesion molecules on the surface of immune cells. Adhesion molecules allow cells to bind to each other, and in the case of MS, allow activated lymphocytes to bind to endothelial cells, which is a key step in these cells' entering the central nervous system to cause immune damage to the brain. Research suggests that Tysabri works by preventing these immune cells from migrating from the blood stream into the brain where they otherwise might cause inflammation and potentially damage

nerve fibers and their insulation. Tysabri is a biologic administered by intravenous infusion over a period of approximately one hour and is indicated for the treatment of patients with relapsing forms of MS to reduce the frequency of clinical exacerbations. The recommended dose is 300 mg IV infusion every four weeks. It is supplied as a sterile, colorless, and clear to slightly opalescent concentrate for IV infusion. Each package contains 300mg of Tysabri in a single-use vial.

Request #05.53

Amar Singh of Abraxis Oncology submitted a request to establish a code for Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound), Trade Name: ABRAXANE™ for Injectable Suspension. According to the requester, ABRAXANE™ is the first in a novel class of solvent-free compounds that combines human albumin with an active pharmaceutical agent (paclitaxel) in the nanoparticle state. This novel form of drug reduces toxicity and enhances efficacy by increasing intra-tumoral concentration of the drug while sparing normal tissue. ABRAXANE™ is an anti-cancer chemotherapeutic agent that inhibits microtubule formation, thereby killing rapidly dividing cancer cells. Each single-use vial of ABRAXANE™ contains 100mg of paclitaxel and approximately 900 mg of human albumin. Each milliliter of reconstituted suspension contains 5mg of paclitaxel. This formulation is free of solvents. ABRAXANE™ is a cytoxic anti-cancer drug given via intravenous infusion of 260mg/m² over 30 minutes every three weeks. Unlike other taxanes, no premedication is required prior to administration.

Request #05.54

Kathy Francisco of The Pinnacle Health Group, Inc. has submitted a request to establish a code Perflexane Lipid Microspheres, Trade Name: Imagent®. According to the requester, Imagent is a kit for the preparation of perflexane lipid microspheres for injectable suspension. It is a sterile, non-pyrogenic white powder with a diluted perflexane headspace that, after reconstitution into a suspension of microspheres is used for contrast enhancement during the indicated ultrasound imaging procedures. It is indicated for use in subjects with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. Imagent must be reconstituted and withdrawn from the vial via the supplied vented 5µm filter dispensing pen. The recommended dose is 0.00625 mL/kg (0.125 mg/kg) administered as a single intravenous bolus over a period of not less then 10 seconds and immediately followed by a saline flush. Imagent must be used within 60 minutes of reconstitution. Imagent kit for the preparation of Perflexane-Lipid Microspheres Injectable Suspension is supplied for single-use and each kit contains a 10-mL glass vial containing 200mg of Imagent powder, a 20-mL plastic vial of Sterile Water for Injection, and 10-mL disposable plastic sterile syringe, a sterile, vented 5µm filter dispensing pen, and a package insert.

Request #05.55

Joseph J. Canny of Watson Pharma, Inc. has submitted a request to establish a unique code for Iron Dextran Injection, USP, Trade Name: INFeD®. According to the requester, INFeD® is FDA approved for the treatment of patients with documented iron deficiency in which oral administration is unsatisfactory or impossible. INFeD® can be administered intravenously or intramuscularly. The recommended dose for iron-deficiency anemia varies by patient age, gender, and weight and is calculated using the following table that incorporates the patient's desired hemoglobin and observed hemoglobin. It is supplied in 2mL single dose amber vials in cartons of 10, containing 50mg of elemental iron per mL.

Request #05.56
Terry Tenbrunsel of Bayer Healthcare LLC has submitted a request to establish a J code for Immune Globulin Intravenous [Human], 10% Caprylate/Chromatography Purified, Trade Name: Gamunex®. According to the requester, Gamunex is indicated as a replacement therapy for primary immunodeficiency states in which severe impairment of antibody forming capacity has been shown. It is indicated in idiopathic thrombocytopenic purpura to rapidly raise platelet counts to prevent bleeding or allow a patient with ITP to undergo surgery. It is administered by intravenous infusion only. It is recommended that it initially be infused at a rate of 0.01 mL/kg per minute for the first 30 minutes. If well-tolerated, the rate may be gradually increased to a maximum of 0.08 mL/kg per minute. It is supplied as a solution for intravenous administration.

Request #05.57
Nick Poulios of Elan Pharmaceuticals, Inc. submitted a request to establish a code for zoconotide intrathecal infusion, Trade Name: PRIALT®. According to the requester, PRIALT® (ziconotide intrathecal infusion) is in a new class of non-opioid analgesics called N-type calcium channel blockers (NCCBs) and will be used for the treatment of severe chronic pain, in patients for whom intrathecal (IT) therapy is warranted, and who are intolerant of or refractory to other treatments, such as systemic analgesics, adjunctive therapies or IT morphine. It is a synthetic equivalent of a naturally occurring conopeptide, found in a marine snail known as *Conus magus*. While the mechanism by which PRIALT exerts its anti-nociceptive effect(s) has been well established in animals, the mechanism in humans is not completely known. It is believed that PRIALT relives chronic pain by blocking the release of neurotransmitter signals in the spinal cord. PRIALT does not bind to opioid receptors. PRIALT is formulated as a sterile, preservative-free, isotonic solution. It is then either used undiluted or diluted to the appropriate concentration with 0.9% Sodium Chloride Injection, USP (preservative free).

Request #05.58A
Tom Comcowich of RJ Health Systems International, LLC has submitted a request to (A) revise the descriptor of existing code J3303 to add the word "intralesional", and change the strength from "per 5 mg" to "per 0.5 mg", to more accurately describe triamcinolone hexacetonide, trade name: Aristospan, its common use, and billing increments. Also

requests (B) a new code for the 20 mg/mL product. According to the requestor, Aristospan is a glucocorticoid (steroid) which exerts an anti-inflammatory activity and is used in a number of different inflammatory conditions. It is injected intralesionally to decrease inflammation.

Request #05.58B
Tom Comcowich of RJ Health Systems International has submitted a request to establish a code for triamcinolone hexacetonide, Trade Name: Aristospan 20mg/mL. According to the requestor, Aristospan is a glucocorticoid (steroid) which exerts anti-inflammatory activity and is used in a number of different inflammatory conditions. It is indicated for use as adjunctive therapy for short-term administration. Aristospan 20mg/mL is injected intra-articularly and is supplied in 1mL and 5mL vials.

Request #05.59
Christopher Panarites of Scios, Inc. submitted a request to change the description of existing code J2324 from "Injection, nesiritide, *0.25mg*" to "Injection, nesiritide, *0.1mg*. According to the requester, NATRECOR® (nesiritide) is a sterile, purified preparation of a new drug class, human B-type natriuretic peptide (hBNP), and is manufactured from E. coli using recombinant DNA technology. NATRECOR® is a potent vasodilator used to treat acutely decompensated congestive heart failure. NATRECOR® is indicated for the intravenous treatment of patients with acutely decompensated congestive heart failure who have dyspnea (shortness of breath) at arrest or with minimal activity. In this population, the use of NATRECOR® reduced pulmonary capillary wedge pressure and improved dyspnea. According to the applicant, the current dose descriptor of 0.25mg is not sufficiently precise to accommodate individual dosing based on patient weight and intended duration of infusion and other requirements for dose adjustments. In addition, the requested 0.1 mg dose will accommodate the current vial size of 1.5mg as well as the 0.6mg vial now in development, which will meet the needs of most patients and their providers.

Request #05.61
Gabriele G. Niederauer, Ph.D. of OsteoBiologics, Inc. has submitted a request to establish a code for a Polygraft® BGS Bone Graft Substitute, Trade Name: TruFit® BGS Plug. The requester claims that there is not a CPT-4 code which identifies the particular procedures in which this product is used, and no HCPCS Level II codes to identify the implant. According to the requester, TruFit® BGS Plugs are made of PolyGraft® BGS, which is a proprietary combination of PLA (Polylactic acid), PGA (polyglycolic acid), Calcium Sulfate and trace amounts of surfactant. The production process used to make the TruFit Plugs is also proprietary. The plugs are cylindrical in shape and sized to specifically fit into osteochondral harvest sites or osseous defects created surgically using the TruKor ™ Site Preparation Kit. The TruFit® BGS Plug material acts as a scaffold and provides a protected environment in which new tissue may grow. The surfactant, which makes the material hydrophilic, allows nutrients to be wicked up into the pores and

held to encourage growth. The material absorbs over a 9 month period, which is the time necessary to grow into and replace the scaffold.

Request #05.62

Barbara Rohan of Smith and Nephew, Inc. has submitted a request to establish a code for Computer Assisted External Fixation Struts, Trade Name: Taylor Spatial Frame (TSF) Standard and Fast Fx Struts. The requester claims that there is no existing HCPCS code which describes the struts used with computer assisted external fixation systems, which has created problems, for physicians seeking payment for these items. Applicant requests the following language: Lxxxx "COMPUTER ASSISTED EXTERNAL FIXATION STRUT, EACH". According to the requester, the External fixation systems stabilize bone fractures, bringing them into proper alignment and correcting limb deformities. The Taylor Spatial Frame is an external fixation system that consists in part of pins that are inserted into the bone above and below a fracture, rings or plates that attach to the pins and encircle the limb, and telescoping and pivoting struts that connect the rings or plates together. It is used to stabilize fractures and correct multi-planar and transitional deformities simultaneously. It is the only system that also includes computer software that assists physicians in calculating a prescription for strut adjustment and replacement that allows gradual correction of fractures and deformities. The software transforms measurements of a patients fracture or deformity into a prescription for: 1) when and how much a patient should lengthen or shorten his or her struts; and 2) when a patient should come into a doctor's office to have one of his or her struts replaced.

Request #05.63

Linda Sherburne of Breg, Inc. submitted a request to: A) Establish a code for a knee brace, trade name: Breg's X2K Custom Counterforce Plus and B) Establish a code for a knee brace, trade name: Breg's X2K OA. The requester claims that, "While there are HCPCS codes that identify "with or without" varus/valgus adjustment, (single upright), no base code exists that appropriately identifies the double upright product." According to the requester, Breg's X2K knee braces are used for unicompartmental osteoarthritis, degenerative joint disease, ACL with Associated condral defect, post-op high tibal osteotomy, articular defect and/or repair, and osteochondral grafting and etc. Breg's X2K Custom Counterforce Plus is a custom fabricated functional knee brace that addresses not only the pain associated with unicompartmental osteoarthritis, but also the stability needs of the beneficiary. Breg's X2K OA is a prefabricated functional knee brace that addresses pain associated with unicompartmental osteoarthritis, and the stability needs of the beneficiary. These braces affect the varus/valgus movement, at the knee, which helps to reduce pain and restore normal function. In order to relieve pain in the affected compartment, the diamond shape ensures rigidity to the frame allowing the application of a positive varus or valgus load from the unaffected side. Breg's X2K offers double upright aluminum frames, adjustability of load, 2 polycentric joints, 5 numbered straps and strap pads, medical grade silicone added to the strap pads, enlarged tibial frame pad and thigh frame pad.

Request #05.64

Mitchell Dobson of Hanger Prosthetics & Orthotics submitted a request to clarify with a new code or code revision a Symes level amputation, and suggests a revision of code L5700 to read "REPLACEMENT SOCKET, BELOW KNEE/SYMES, MOLDED TO PATIENT MODEL". This code currently reads: REPLACEMENT, SOCKET, BELOW KNEE, MOLDED TO PATIENT MODEL. According to the requester, the socket portion of the prosthesis is the most critical part of a prosthesis as its function is to distribute axial load, transverse sheer, and regular forces onto the residual limb during gait and other activities of daily living. There are existing codes for many other levels of lower extremity amputation, however (according to the requester) the Symes level does not currently have a replacement code. The Symes socket is used for Symes (ankle disarticulation) level amputations and benefits the patient by allowing distribution of ground reaction forces over the residual limb allowing patients to ambulate and participate in other normal activities.

Request #05.65

Larry Lange of Prosthetic Design submitted a request to establish a code for a dynamic response endoskeletal connector for prostheses, trade name: FlexCon Endoskeletal Adapter. The requester claims that there is no HCPCS code that accurately describes the functions of the FlexCon™ adapters. According to the requester, the FlexCon endoskeletal adapter is a unique, patented component that permits restricted range of motion in the hip joint on the amputated side. It also provides stance flexion in early stance and a dynamic response effect in late stance. Because the FlexCon is made from high strength, lightweight carbon fiber composite material, it can also function as a leaf spring to increase the overall flexibility of the prosthesis. FlexCon is available in multiple configurations to accommodate differing amounts of joint contracture and varying residual limb lengths; and is used primarily for individuals who have a knee disarticulation or higher level of amputation combined with a significant flexion or flexion-abduction contracture of the ipsilateral hip joint. This component can also be retrofitted into an existing endoskeletal prosthesis, to accommodate changes in the amount of contracture or to correct a mal-aligned prosthesis without replacing the entire artificial limb. When the proper Flexcon adapter is used, the hip flexion contracture can be fully accommodated and the knee center located in the optimal position, posterior to the weight bearing line.

Request #05.66

Kevin Corcoran submitted a request to establish a code for intrastromal corneal ring segments, trade name: Intacs. The requester claims that intrastromal corneal ring segments are not included in the ASC facility payment amount as stipulated in MBPM 260.4 (formerly MCM 2265.2), and that the addition of a code is necessary to facilitate Medicare Part B claims in ASCs and also for physician's office and hospital outpatient billing. The requester suggests a new code with the following language "INTRASOMAL CORNEAL RING SEGMENTS". According to the requester, Intacs are intrastromal

corneal ring segments designed to reshape the curvature of the cornea to reduce myopia and astigmatism caused by keratoconus. They are clear, thin, psaolymethylmethacrylate (PMMA), crescent shaped, prescription inserts that are surgically implanted in the periphery of the cornea by an ophthalmologist in an outpatient procedure. The placement and dimensions of the Intacs implants help to reshape the cornea to its original, natural shape, thereby normalizing the cornea's architecture. Using proprietary surgical instruments, a small 1.2 millimeter incision is made in the cornea at 70% depth and channels are created for the insertion of the Intacs. Intacs are then threaded into the channels, and the incision is closed using 10-0 suture. Surgical treatment of keratoconus with Intacs is reversible and less invasive than penetrating keratoplasty or corneal transplant.

Request #05.67

Darlene Sassi of Sassi Pacer, Inc. submitted a request to establish a code for an outer support system, trade name: Sassi Pacer Drop Foot Support System. The requester claims there is currently no code to fully describe the Sassi Pacer. According to the requester, the Sassi Pacer gives anyone with drop foot the opportunity to walk with a more normal gait more comfortably. Every component of the Sassi Pacer is soft and pliable. It moves naturally with all joints, muscles, and ligaments. Sassi Pacer is easily worn, and the soft cotton and flannel lined ankle band draws in the soft rubber tubing without interfering with the tension needed to support the foot allowing the patient to wear slacks. The Sassi pacer is machine-washable and easily placed on or taken off simply by pulling two Velcro tabs and unhooking one clip. The Pacer is a deterrent of atrophy by allowing 100% range of movement of all muscles, joints and ligaments at all times, enabling a patient to achieve their maximum recovery status. It also stops the ankle from locking up from lack of movement that is common with current ankle foot orthoses. With the Pacer, pressure sores and chaffing are nearly eliminated.

#05.68

Kevin Corcoran of Corcoran Consulting Group submitted a request to establish a code for a capsular tensular ring, trade name: Morcher Capsular Tension Ring. The requester claims that capsular tension rings are not included in the ASC facility payment amount as stipulated in MBPM 100-4, 260.4 (formerly MCM 2265.5); however there is a provision for reimbursement for HOPPS as an incidental component of APC 246. Requester is seeking a new HCPCS code to facilitate ASC claims under Medicare Part B, and suggests the following language: "CAPSULAR TENSION RING". According to the requester, capsular tension rings consist of an incomplete loop made out of a flexible polymethyl methacrylate filament with eyelets at each end. The device is indicated for the stabilization of the human crystalline lens capsule in the presence of weak or partially absent zonules in adult patients undergoing cataract extraction with intraocular lens implantation. Conditions associated with weak or partially absent zonules may include primary zonular weakness, secondary zonular weakness, zonulysis, pseudoexfoliation and Marchesani Syndrome.

#05.69 A-C

Stephanie Bucklin of Hanger Prosthetics and Orthotics, Inc. submitted a request to to establish 3 new codes for upper extremity prosthetic addition of carbon acrylic socket laminations for below elbow; above elbow; and shoulder disarticulation levels, and request for the following language: A) ADDITION TO UPPER EXTREMITY PROSTHESIS, CARBON ACRYLIC SOCKET LAMINATION, FOR ELBOW FRAME OR FOREARM SECTION, B) ADDITION TO UPPER EXTREMITY PROSTHESIS, CARBON ACRYLIC SOCKET LAMINATION, FOR ABOVE ELBOW FRAME OR HUMERAL SECTION, AND C) ADDITION TO UPPER EXTREMITY PROSTHESIS, CARBON ACRYLIC SOCKET LAMINATION, FOR SHOULDER DISARTICULATION OR HIGHER CAP-STYLE FRAME. According to the requester, carbon acrylic socket lamination is obtained during the fabrication of the outer frame of an upper extremity prosthesis. The carbon acrylic socket lamination for a forearm section (for elbow or wrist disarticulation), humeral section (for above elbow or elbow disarticulation), or shoulder cap-style frame (for shoulder disarticulation or higher) benefits the patient because of its lightweight; and improved material strength and durability. When used with flexible inner sockets or gel socket insert systems, openings may be cut in the carbon fiber material without compromising the strength of the frame, allowing the inner socket or liner to expand and retract with muscle contractions.

Request #05.70 A-F

Stephanie Bucklin of Hanger Prosthetics and Orthotics, Inc. submitted a request to establish 6 codes for replacement sockets; with requested language as follows: A) REPLACEMENT, SOCKET, BELOW ELBOW/WRIST DISARTICULATION, NOT FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL, B) REPLACEMENT, SOCKET, BELOW ELBOW/WRIST DISARTICULATION, FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL, C) REPLACEMENT, SOCKET, ABOVE ELBOW/ELBOW DISARTICULATION, NOT FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL, D) REPLACEMENT, SOCKET, ABOVE ELBOW/ DISARTICULATION, FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL, E) REPLACEMENT, SOCKET, SHOULDER DISARTICULATION/INTERSCAPULAR THORACIC, NOT FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL, F) REPLACEMENT, SOCKET, SHOULDER DISARTICULATION/INTERSCAPULAR THORACIC, FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL. According to the requester, an upper extremity prosthetic socket replacement is necessary when an amputee encounters poor socket fit in their existing prosthesis. Inadequate fit of a prosthetic socket results in patient discomfort as well as poor control of the prosthesis. Inherent with the design and function of an upper extremity prosthesis, the inner socket must maintain an intimate anatomical fit and the prosthetic componentry must be maintained to allow for optimum functional performance. The intimate fit of a socket will help the patient in using the prosthesis to the fullest by supporting the control of the prosthetic components. The contoured inner socket allows patients to be more

active in their daily lives and may even help to reduce any pain that the patient may be experiencing due to the ill-fitting socket.

Request #05.71

Chris Blake of the American Society of Hand Therapists submitted a request to establish a code for an elbow orthosis (EO), static, custom-fabricated. According to the requester, the EO, static, custom fabricated is a rigid circumferential, dorsal or volar framed orthosis with soft straps and closures for the arm, elbow and forearm initiating proximal to the elbow joint, crossing the elbow joint, secured along the arm and forearm and extends to, but does not cross the wrist. Statically stabilizes and may limit motion of the elbow. The orthosis is custom fabricated, includes fitting, training, and a limited number of size and position modifications. It does not include modifications that necessitate additional material for patient's changing anatomical, medical, and post surgical needs. Specifically the EO, static, custom fabricated is used to protect medical conditions of the elbow, distal humerus, humeroulnar joint, proximal radioulnar joint and/or proximal end and shafts of the radius and ulna during the healing process or reduce contractures and stiffness of these structures.

Request #05.72

Chris Blake of the American Society of Hand Therapists submitted a request to establish a code for a Shoulder Orthosis (SO), static, custom-fabricated. According to the requester, the SO, static, custom fabricated is a rigid circumferential, dorsal or volar framed orthosis with soft straps and closures for the shoulder initiating proximal to the glenohumeral joint, crossing the glenohumeral joint, secured along the humerus and extends to, but does not cross the elbow. Statically stabilizes or limits motion of the shoulder. The orthosis is custom fabricated, includes fitting, training, and a limited number of size and position modifications. It does not include modifications that necessitate additional material for patient's changing anatomical, medical, and post surgical needs. Specifically the SO, static, custom fabricated is used to protect medical conditions of the shoulder during the healing process and/or to prevent contractures and stiffness of the shoulder.

Request #05.73

Chris Blake of the American Society of Hand Therapists submitted a request to establish a code for a Shoulder Orthosis (SO), dynamic, custom-fabricated. According to the requester, the SO, dynamic, custom fabricated is a rigid circumferential, dorsal or volar framed orthosis with soft straps and closures for the shoulder initiating proximal to the glenohumeral joint, crossing the glenohumeral joint, secured along the humerus and extends to, but does not cross the elbow. Statically stabilizes the shoulder and uses a dynamic (static progressive) component (springs, rubber bands, hinges, turn keys or static progressive pull) at the shoulder. The orthosis is custom fabricated, includes fitting, training, and a limited number of size and position modifications. It does not include

modifications that necessitate additional material for patient's changing anatomical, medical, and post surgical needs. Specifically the SO, dynamic, custom fabricated is used to protect medical conditions of the shoulder during the healing process or reduce contractures and stiffness of the shoulder.

Request #05.74
Chris Blake of the American Society of Hand Therapists submitted a request to establish a code for a Shoulder Elbow Wrist Hand Orthosis (SEWHO), static, custom-fabricated. According to the requester, the SEWHO, static is a rigid anterior or posterior framed orthosis with soft straps and closures initiating proximal to the glenohumeral joint and axillary region, extending through the upper arm, crossing the elbow and wrist joints. Statically stabilizes and/or limits motion of the shoulder, elbow, wrist and hand. The orthosis is custom fabricated, includes fitting, training, and a limited number of size and position modifications. It does not include modifications that necessitate additional material for patient's changing anatomical, medical, and post surgical needs. Specifically the SEWHO, static, custom fabricated is used to protect medical conditions of the shoulder, elbow, wrist and hand during the healing process and/or reduce contractures and stiffness of the shoulder, elbow, wrist and hand.

Request #05.75
Chris Blake of the American Society of Hand Therapists submitted a request to establish a code for a Shoulder Elbow Wrist Hand Finger Orthosis (SEWHFO), static, custom-fabricated. According to the requester, the SEWHFO, static, custom fabricated is a rigid anterior or posterior framed orthosis with soft straps and closures initiating proximal to the glenohumeral joint and axillary region, extending through the upper arm, crossing the elbow, wrists and hand joints including the finger(s). Statically stabilizes and may limit motion of the shoulder, elbow, wrist, hand and/or finger(s). The orthosis is custom fabricated, includes fitting, training, and a limited number of size and position modifications. It does not include modifications that necessitate additional material for patient's changing anatomical, medical, and post surgical needs. Specifically the SEWHFO, static, custom fabricated is used to protect medical conditions of the shoulder, elbow, wrist, hand and finger(s) during the healing process and/or reduce contractures and stiffness of the shoulder, elbow, wrist, hand and finger(s).

Request #05.76
Chris Blake of the American Society of Hand Therapists submitted a request to establish a code for a Shoulder Elbow Wrist Hand Finger Orthosis (SEWHFO), dynamic, custom-fabricated. According to the requester, the SEWHFO, dynamic is a rigid anterior or posterior framed orthosis with soft straps and closures initiating proximal to the glenohumeral joint and axillary region, extending through the upper arm, crossing the elbow, wrists and hand joints including the finger(s). Statically stabilizes one or more joints while using a dynamic (static progressive) component (springs, rubber bands, hinges, turn keys or static progressive pull) to apply a dynamic force to one or more

joints. The orthosis is custom fabricated, includes fitting, training, and a limited number of size and position modifications. It does not include modifications that necessitate additional material for patient's changing anatomical, medical, and post surgical needs. Specifically the SEWHFO, dynamic, custom fabricated is used to protect medical conditions of the shoulder, elbow, wrist, hand and finger(s) during the healing process and/or reduce contractures and stiffness of the shoulder, elbow, wrist, hand and finger(s).

Request #05.77
Chris Blake of Carolina Hand Therapy has submitted a request to establish a code for an elbow wrist hand orthosis, Trade Name: Elbow wrist hand orthosis (EWHO), static custom-fabricated. According to the requester, the EWHO-static is a rigid anterior or posterior framed orthosis with soft straps and wrist joints. The orthosis statically stabilizes the elbow and wrist, but does not cross the metacarpal joints of the digits. It is custom-fabricated, including fitting, training, and a limited number of size and position modifications. It does not include modifications that necessitate additional material for patient's changing anatomical, medical, and post surgical needs. It is used to protect medical conditions of the elbow and wrist during the healing process. These types of orthoses have been custom fabricated since the 1930's.

Request #05.78
Chris Blake of Carolina Hand Therapy has submitted a request to establish a code for an elbow wrist hand orthosis (EWHO), dynamic, custom-fabricated, Trade Name: Elbow wrist hand orthosis (EWHO), dynamic, custom-fabricated. According to the requestor, EWHO-dynamic, is a rigid anterior or posterior framed orthosis with soft straps and closures initiating distal to the axillary area, crossing the elbow and wrist joints. The orthosis is custom fabricated, includes fitting, training, and a limited number of size and position modifications. It is used to protect medical conditions of the elbow and wrist during the healing process or reduce contractures and stiffness of the forearm.

Request #05.79
Chris Blake of Carolina Hand Therapy has submitted a request to establish a code for an elbow wrist hand finger orthosis (EWHFO), static, custom-fabricated, Trade Name: same. According to the requestor, EWHFO-static, is a rigid anterior or posterior framed orthosis with soft straps and closures initiating distal to the axillary area, crossing the elbow, wrist and metacarpal phalengeal joints. The orthosis is custom fabricated, and includes fitting, training, and a limited number of size and position modifications. It does not include modifications that necessitate additional material for the patient's changing anatomical, medical and post surgical needs. It is used to protect medical conditions of the elbow, wrist and hand during the healing process and/or to prevent contractures and stiffness of the elbow, forearm, wrist or hand.

Request #05.80

Chris Blake of Carolina Hand Therapy has submitted a request to establish a code for an Elbow Wrist Hand Finger Orthosis (EWHFO), dynamic, custom-fabricated. According to the requestor, EWHFO-dynamic is a rigid anterior or posterior framed orthosis with soft straps and closures initiating distal to the axillary area, crossing the elbow, wrist and metacarpal phalengeal joints. The orthosis is custom-fabricated, includes fitting, training, and a limited number of size and position modifications. It does not include modifications that necessitate additional material for patient's changing anatomical, medical and post surgical needs. It is used to protect medical conditions of the elbow, wrist, and hand during the healing process and/or to reduce contractures and stiffness of the elbow, forearm, wrist, or hand. These may include but are not limited to multiple system injures to bone or soft tissue which includes distal humerus or proximal radius/ulna fractures and/or damage to nerve, tendon, or muscle of the forearm due to trauma or compression to these systems. The dynamic component can be used to allow for early protected motion while these structures are healing to assist in the prevention of adhesions and contractures, can work to reduce contractures that have developed, or can substitute for loss musculature.

Request #05.81
Chris Blake of Carolina Hand Therapy has submitted a request to establish a code for a Wrist Hand Orthosis (WHO), dynamic, custom-fabricated. According to the requestor, WHO-dynamic is a rigid dorsal or volar framed orthosis with soft strap material and closures initiating approximately three inches distal to elbow, crossing the wrist joint. The orthosis is custom-fabricated, includes fitting, training, and a limited number of size and position modifications. It does not include modifications that necessitate additional material for patient's changing anatomical, medical, and post surgical needs. It is used to increase mobility or protect structures by limiting mobility secondary to medical conditions affecting the wrist during the healing process. These may include but are not limited to distal radius/ulna/carpal fractures, carpal ligament tears/repairs, wrist flexor/extensor injuries/repairs, burns, skin grafts, and ganglion cyst removal.

Request #05.82
Chris Blake of the American Society of Hand Therapists submitted a request establish a code for a Hand Orthosis (HO), static, custom-fabricated. According to the requester, the hand orthosis is a static, rigid anterior and/or posterior framed orthosis with soft straps and closures in the hand area. The orthosis is limited to the hand area and does not cross the metacarpal joints of the digits or the wrist joint. This orthosis is custom fabricated, includes fitting, training, and size and position modifications, but does not include modifications that include additional material for patient's specific anatomical, medical, and post surgical needs. The Hand orthosis static is used to protect medical conditions of the hand or carpal metacarpal joint of the thumb during the healing process or to reduce pain. These may include but are not limited to injuries to bone, degenerative joint disease, or soft tissue trauma. While there may be current prefabricated orthoses available, the custom-fabricated is individually designed and fitted to the patient due to an injury or medical condition.

Request #05.83

Chris Blake of the American Society of Hand Therapists submitted a request to establish a code for a Hand Finger Orthosis (HFO), static, custom fabricated. According to the requester, this hand finger orthosis is a static, rigid anterior and/or posterior framed orthosis with soft straps and closures in the hand and finger area, crossing the metacarpal joints. The orthosis is limited to the hand and digits and does not cross the wrist joint. It is custom fabricated, includes fitting, training, and size and position modifications, but does not include modifications that include additional material for patient's specific anatomical, medical, and post surgical needs. The hand finger orthosis-static is used to protect medical conditions of the hand and digits during the healing process, reduce pain, or position to prevent joint derangement. These may include but are not limited to, multiple system injuries to bone, nerve, artery, tendon, degenerative joint disease, or soft tissue trauma. This orthosis is custom fabricated as the patient will be required to wear it for typically a minimum of three weeks and must contour to specific personal anatomy in order to support the injured/inflamed area, prevent the shifting of the fracture site, realignment of deranged joints, and/or prevent skin breakdown. While there may be current prefabricated orthoses available, the custom-fabricated is individually designed and fitted to the patient due to an injury or medical condition.

Request #05.84

Chris Blake of the American Society of Hand Therapists submitted a request to establish a code for a Hand Finger Orthosis (HFO), dynamic custom-fabricated. According to the requester, this hand finger orthosis is a dynamic, rigid volar, dorsal, radially or ulnarly contoured orthosis with soft straps and closures. This orthosis may initiate at the base of the hand and can extend to the middle or distal digital crease(s) or to the tip of the finger(s)/thumb depending upon diagnosis. The orthosis will have a dynamic (static progressive) component (springs, rubber-bands, hinges, turn keys or static progressive pull) for one or a combination of the metacarpal, proximal, or distal interphalangeal joints. The hand finger orthosis is used to protect medical conditions of the hand/finger/thumb during the healing process or to reduce contractures and stiffness of the hand/finger/thumb. These may include but are not limited to, multiple system injuries to bone of the hand/fingers (fracture) and/or nerve, ligament, tendons or muscles of the hand/fingers due to trauma or compression to these systems. The dynamic component will allow early protected motion while these structures are healing in order to prevent adhesions and contractures. The orthosis is custom fabricated and it must contour to specific personal anatomy in order to prevent damage from soft tissue breakdown and provide rest and balance to the involved tissues.

Request #05.85

Chris Blake of the American Society of Hand Therapists submitted a request to establish a code for a Finger Orthosis (FO), static, custom-fabricated. According to the requester, this finger orthosis is a static, rigid volar or dorsal contoured orthosis with soft straps and

closures. This orthosis may initiate at the proximal or middle digital crease and will extend to the distal digital crease or to the tip of the finger/thumb depending upon diagnosis. The static finger orthosis is used specifically to protect medical conditions of the finger/thumb during the healing process. These may include but are not limited to multiple system injuries to bone of the proximal, middle, or distal phalanges (fracture) and/or nerve, ligament, or tendons of the finger due to trauma or compression to these systems. This static orthosis is applied to protect a joint(s) during the healing process and protect the soft tissue components which anatomically cross the joint(s). The orthosis is custom fabricated and must contour to specific personal anatomy in order to prevent damage from soft tissue breakdown and provide rest and balance to the involved tissues.

Request #05.86

Chris Blake of the American Society of Hand Therapists submitted a request to establish a code for a Finger Orthosis (FO), dynamic, custom-fabricated. According to the requester, this finger orthosis is a dynamic, rigid volar or dorsal contoured orthosis with soft straps and closures. This orthosis may initiate at the proximal or middle digital crease and will extend to the distal digital crease or to the tip of the finger/thumb depending upon diagnosis. The dynamic finger orthosis will have a dynamic (static progressive) component (springs, rubber-bands, hinges, turn keys or static progressive pull) at the distal phalangeal joint, proximal phalangeal joint, or both. This orthosis is custom fabricated, includes fitting, training, and size and position modifications. Dynamic finger orthoses are used specifically to protect medical conditions of the finger/thumb during the healing process or to reduce contractures and stiffness of the finger/thumb. These may include, but are not limited, to multiple system injuries to bone of the proximal, middle, or distal phalanges (fracture) and/or nerve, ligament, or tendons of the finger due to trauma or compression to these systems. The dynamic component will allow early protected motion while these structures are healing in order to prevent adhesions and contractures. This orthosis is custom fabricated and must contour to specific personal anatomy in order to prevent damage from soft tissue breakdown and provide rest and balance to the involved tissues.

Request #05.87

Bernie Tatro of Jerome Medical has submitted a request to establish a code for non-conductive Halo Traction Ring and Skull Pins, Trade Name: Resolve Halo System. According to the requester, these products are part of a system generally described as Halo Traction or Halo Vest Systems. A complete system consists of the halo ring, skull pins, superstructure and vest. The halo system is used in the stabilization and treatment of unstable cervical spine injuries. The Ring and Skull Pins serve as the rigid fixation point at the head. The vest is secured to the upper torso. The superstructure is used to maintain the prescribed head and spinal alignment. The patient may wear the unit for six to twelve weeks without removal. During that time the patient may require diagnostic procedures such as magnetic resonance imaging. The requester is seeking a new code “to provide reimbursement when newer non-conductive materials are required for patient safety and optimal imaging” and that “would compensate for the increased expense of

high-tech insulative materials". Requester suggests the following language: "ADDITION TO HALO PROCEDURES, NON-CONDUCTIVE RING AND SKULL PINS".

Request #05.88 A&B

Stephanie Bucklin of Hanger Prosthetics & Orthotics, Inc., submitted a request to establish a code for (**a**) a prosthetic donning sleeve, double layer low friction material, upper limb, each and (**b**) a prosthetic donning sleeve, double layer low friction material, lower limb, each, Trade Name: Donning Slip Socks, Double layer low friction donning aid. According to the requester, Hanger's "Donning Slip Socks" are double layer prosthetic donning aids that vary in size and are used to don (put on) an upper extremity (arm) or lower extremity (leg) prosthesis. The reason these types of donning aids are superior to the traditional cotton stockinette (used for donning in the past) is because this product is made of a durable nylon sailcloth, which lasts longer and causes less friction. These donning aids are an "off-the-shelf" item that is fit to the patient by the prosthetist from measurements.

Request #05.89
Stephanie Bucklin of Hanger Prosthetics and Orthotics submitted a request for a reconsideration for the establishment of a code for an addition to upper extremity prosthesis, glove for terminal device, prefabricated with durability and stain resistance features. Appicant requests the following language: "ADDITION TO UPPER EXTREMITY PROSTHESIS, GLOVE FOR TERMINAL DEVICE, PREFABRICATED, WITH DURABILITY AND STAIN RESISTANCE FEATURES". According to the requester, upper extremity prosthetic coverings are used to cover and protect the delicate internal components of an arm prosthesis. Gloves, made of polyvinyl chloride, have been used for decades to cover static and dynamic prosthetic hand components. A Polyvinyl chloride (PVC) production glove provides a natural appearance to an upper extremity prosthesis. Standard PVC production gloves provide shock absorption and water resistance to protect the prosthetic hand from dust and moisture. Micro-coated PVC production gloves provide similar benefits as standard PVC gloves. However, when a micro-coating process is performed on the Centri Micro-coated PVC production glove, it is said to make the glove "stain resistant, easier to clean, and less friction against clothing than a standard PVC production glove. The micro-coated PVC production gloves are more durable than standard PVC production gloves. Use of silicone production gloves provide significant advantages in durability, function and cosmesis. Silicone production gloves offer: inherent stain resistance, increased durability, natural appearance, improved friction characteristics, water resistance, and improved elasticity.

Request #05.90 A-C
Mark Domyahn of Medtronic submitted a request to establish 3 codes for: A) Single array, implantable non-rechargeable neurostimulator pulse generator, B) dual array, implantable non-rechargeable neurostimulator pulse generator, and C) Implantable

extension for neurostimulator systems. According to the requester, Neurostimulation is used to aid in the management of movement disorders, chronic intractable pain, and urinary dysfunction, among other disorders associated with nervous function. An implantable neurostimulation system consists of four components, three of which are implanted into a patient's body, a lead, a power source and a tunneled extension that conducts the electrical pulses between the neurostimulator and the lead. The patient programmer is an external device used by the patient to control the therapy. Neurostimulators can be single-array or dual-array.

A single-array neurostimulator is attached to one lead only. Single array neurostimulators are appropriate for disorders that require a single site of stimulation. The Soletra neurostimulator is used in deep brain stimulation therapy to treat patients with advanced Parkinson's disease and essential tremor. Intrel 3 neurostimulator is used to treat chronic intractable pain associated with underlying disorders such as radiculopathy, peripheral neuropathy, arachnoiditis, complex regional pain syndrome, and failed back syndrome. Interstim neurostimulator is used to manage urinary retention and the symptoms of an overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone.

A dual-array neurostimulator is attached at two leads. For patients who require bilateral stimulation or stimulation at two separate sites, two leads and two extensions are implanted but only one neurostimulator. Kinetra neurostimulator is used in Deep Brain Stimulation therapy to treat patients with advanced Parkinson's disease and patients with essential tremor. Synergy neurostimulator is used to treat chronic intractable pain associated with underlying disorders such as radiculopathy, peripheral neuropathy, arachnoiditis, complex regional pain syndrome and failed back syndrome. Synergy Versitrel neurostimulator is used to treat chronic intractable pain.

The extension is implanted into the patient at the same time that the neurostimulator and leads are implanted. Extensions are insulated conductors, which are tunneled subcutaneously in the patient's body between the neurostimulator and the lead. One extension is required for each lead. Models 7489 and Model 7471 are extensions utilized in spinal cord neurostimulation systems used to treat patients with intractable pain in the trunk or limbs. Model 7482 is used in Deep Brain Stimulation therapy and Model 3095 is used with systems for urinary control.

Request #05.91 A-C
Tom Walsh of Advanced Bionics Corporation submitted a request to: A) Establish a code for an implantable neurostimulator pulse generator, trade name: Precision, B) Revise code E0756 to read: IMPLANTABLE NEUROSTIMULATOR PULSE GENERATOR WITH NON-RECHARGEABLE BATTERY, currently reads: IMPLANTABLE NEUROSTIMULATOR PULSE GENERATOR and C) Establish a code for an implantable neurostimulator charging system. According to the requester, Precision rechargeable IPG is an implantable neurostimulator pulse generator that is part of a spinal cord stimulation system used to provide electrical stimulation of the spinal cord for the

management of chronic, intractable pain. Precision is designed to deliver current to implanted lead(s) and replace pain sensations with paresthesia, or a cool tingling sensation. It aids in the management of chronic intractable pain of the trunk and/or limbs associated with failed back surgery syndrome, intractable low back pain and leg pain. The Precision is a new generation of neurostimulator that represents an improvement over existing RF generators and non-rechargeable IPGs by providing a rechargeable battery that dramatically increases lifespan of the neurostimulator in clinical practice while allowing for higher power stimulation settings and neurostimulation through multiple independent current sources. According to the requester, the Precision IPG charging system is part of a spinal cord stimulation system used to provide electrical stimulation of the spinal cord for the management of chronic, intractable pain. This external patient charging system is used by the patient to recharge the battery in the Precision rechargeable IPG. The charging system contains a charger with a lithium battery that is recharged in a base station. The charger converts electrical energy to radio frequency energy. The generator converts the RF energy to electrical energy, which recharges its internal battery.

Request #05.92
Sara Christine Oxton of Otto Bock Health Care has submitted a request to establish a code for a wheelchair cushion with phase change materials (PCMs) for skin protection through temperature control, Trade Name: ComforT Cushion. According to the requestor, the ComforT is a wheelchair cushion made with phase change materials for skin protection. The requestor claims that lab studies prove that the ComforT absorbs enough heat to keep the seat interface temperature 10-degrees cooler on average than standard skin protection systems. This cooler temperature blocks moisture formation, which is a key contributor to skin breakdown and pressure sore formation. The PCMs also serve to slow metabolic activity in the seat interface area. The ComforT is used by people whose primary mobility device is a wheelchair. Indications for use include high need for skin protection, or strong propensity toward heat build up while sitting.

Request #05.93
Pete Nohre of Otto Bock Health Care has submitted a request to A.) Combine L6675 UPPER EXTREMITY ADDITION, HARNESS, (E.G. FIGURE OF EIGHT TYPE), SINGLE CABLE DESIGN and L6676 UPPER EXTERMITY ADDITION, HARNESS, (E.G. FIGURE OF EIGHT TYPE), DUAL CABLE DESIGN into one code and B.) establish a new code for an addition to upper extremity, harness, triple control, Trade Name: Triple Control Harness. According to the requestor, this product is a triple control harness system used for controlling an above-elbow body-powered prosthesis and/or an above-elbow hybrid (body powered and myoelectric) prosthesis. It fits the patient around their shoulders and across their back with three cables that run through the harness and are connected to various prosthetic components such as an elbow or cable activated terminal device (hand/hook). Specific movements by the user pull on the cable that causes function of the prosthesis. The triple control incorporates three separate controls for the three different functions that a user needs to perform.

Request #05.94
Pete Nohre of Otto Bock Health Care has submitted a request to establish a code for an electrode replacement, for an upper extremity myoelectric prosthesis. Trade Name: Electrode. According to the requestor, code L6935 covers initial use of electrodes, but not replacement electrodes. The requestor is seeking a code for replacement electrodes.

Request #05.95 A&B
Jeffrey Alaimo of ACOR Orthopaedic, Inc. submitted a request to A) Establish a code for a fabric lining as an add-on to prefabricated orthotics and therapeutic footwear, trade name: X-Static and B) Establish a code for an add-on to custom fabricated orthotics, prosthetics, and therapeutic footwear, trade name: X-Static. According to the requester, X-Static is a polyester material with a layer of pure silver permanently bonded to its threads. It is used as an add-on liner for orthotic devices, prosthetic devices and therapeutic footwear. X-static also provides an interface on the device that is next to the patient's skin. X-Static inherits all the natural attributes of pure silver thus providing users with a broad spectrum antimicrobial, all natural, anti-odor, and thermodynamic footwear that are comfortable, bacteria free, and odor-free.

Request #05.96
James Campbell of Becker Orthopedic submitted a reconsideration request to establish a code for an E-Knee, Trade Name: Becker 9001 E-Knee, with applicant's recommendation for language as follows: "Addition to custom made lower limb orthosis, stance control knee joint mechanism that is automatically engaged during stance phase and disengaged during swing phase, electronically activated." According to the requester, the Becker 9001 E-Knee is an electrically-controlled knee component, with associated hardware, that must be incorporated into a custom-made lower limb orthosis for patient use. The mechanical knee joint provides a lock against flexion that can be disengaged when appropriate but always permit free extension. The 9001 E-Knee is indicated for patients with quadriceps weakness or paralysis, or with similar pathologic conditions that preclude active neuromuscular control of knee stability.

Request #05.97
Tom Traver of Swede-O Inc. submitted a request to establish a code for an Ankle Foot Orthotic, Trade Name: Thermoskin Plantar FXT. According to the requester, the Thermoskin Plantar FXT is used for the treatment of Plantar Fasciitis and/or ankle flexion contracture. It is an alternative to the typical rigid, bulky night splint. It gently pulls the toes back slightly to stretch the Plantar Fascia so it may heal. Due to the low profile of the Plantar FXT, it is also possible to wear a knee orthosis at the same time. The Plantar FXT may also be worn during the day (while seated) to provide longer treatment times. The product is made of a durable fabric with Trioxon lining, a Velcro strap is used to adjust the fit of the AFO around the ankle. A tension strap (Velcro strap)

functions as a lever to maintain foot position and to provide plantar surface support and prevent plantar flexion. This strap can be adjusted to provide different levels of tension. The Trioxon lining creates a micro-climate that maintains an elevated skin temperature while still allowing the skin to ventilate. This climate allows heat therapy to be used on the muscles as they are stretched. The spiral structure of the Trioxon lining wicks moisture away from the skin and traps air within the lining to prevent excessive perspiration.

Request #05.98
Sharon Levy, MD of Dermik Laboratories has submitted a request to establish a code for injectable poly-L-lactic acid, Trade Name: Sculptra™. According to the requestor, Sculptra™ is an injectable implant containing microparticles of poly-L-lactic acid, a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy family. It is intended for restoration and/or correction of the signs of facial fat loss in people with HIV. It is used for HIV patients whose faces are so sunburned that they won't go out in public. It is only FDA approved for HIV patients with lipodystrophy. Sculptra is injected into the deep dermis resulting in a gradual filling of the facial defect. It is supplied as a sterile freeze-dried preparation for injection in a clear glass vial, which is sealed by a penetrable stopper and covered by an aluminum seal with a flip-off cap. Each carton (unit) of Sculptra contains two vials.

Request #05.99
Jeff Ashenbrenner of Otto Bock Health Care has submitted a request to establish a code for a force plate alignment procedure, Trade Name: Otto Bock L.A.S.A.R. Posture. According to the requestor, The L.A.S.A.R. (Laser Assisted Static Alignment Reference) Posture is a microprocessor-controlled alignment instrument offering the prosthetist a method for objectivity evaluating a patient. It is able to detect misalignment problems that current methods will not detect. It is used to assist the prosthetist in the static alignment of lower limb prosthesis. It can be helpful in preparing the prosthesis for fitting as well as trouble-shooting during dynamic alignment or at follow up reviews. In addition, it offers a method in the evaluation of the patient's center of balance in relation to standing balance, spinal curves, and weight distribution.

Request #05.100
Karen Bonn of Restorative Medical, Inc. submitted a request to establish codes to identify HyperHand™ devices HyperHand Solid Thumb; HyperHand Padded Thumb; Ulnar Drift (UD) HyperHand Solid Thumb; and UD HyperHand Padded Thumb; devices and component parts of these devices, either as a kit or as separate devices. According to the requester, the base device of the HyperHand™ designed and manufactured by Restorative Medical, Inc. (RMI) is heat moldable Kydex®. It is not only heat moldable, but holds it shape after it cools while providing the FLEX properties to work with neurological tone. This device also provides the prolonged low load passive stretch required to treat adaptive tissue shortening. It is to be reheated and remolded as the

patient progresses to allow continual gradual progress toward normal alignment. It can be washed off with soap and warm water.

Request #05.101
Gary Horton of Horton Technology Inc. has submitted a request to establish a new add-on L code, applicant suggestion: L238X (Addition to custom fabricated lower limb orthoses or prosthesis, stance control knee joint mechanism that is automatically engaged during stance phase and disengaged during swing phase, mechanically activated), to describe the Horton's Stance Control Orthotic Knee™ Joint System or SCOKJ® System. The applicant also suggests that their proposed language could also apply to the Becker e-knee, however the applicant states that the e-knee microprocessor controlled electronic actuation should have its own unique addition code. An application was not submitted for such code. Horton SCOKJ System consists of mechanical knee joints and associated actuation hardware that must be incorporated into a custom fabricated orthoses or prosthesis to provide knee stability during weight bearing when the patient is unable to do so due to a physical disability.

Request #05.102
Brian Gustin, C.P. of Wisconsin Prosthetics and Orthotics has submitted a request to establish a code for a transtibial/symes hydrostatic prosthetic socket. According to the requestor, the transtibial/symes hydrostatic socket is a specific transtibial socket design that differs from the patella tendon bearing (PTB) socket that is included in the base procedure codes for transtibial prosthesis. The transtibial hydrostatic socket design applies areas of weight bearing over the entire amputated residual limb in a global fashion. It is intended to be used in conjunction with the roll-on type gel liners. The even volume reduction of the transtibial hydrostatic socket vs. the specific weight bearing socket results in a socket fit that has less pressure per square inch as the amputees body weight is evenly applied over the entire surface area. The applicant raises concerns regarding additional incremental costs of this vs. other socket designs.

Request #05.103
R. Adam Fishman of Hypobaric Systems has submitted a request to establish a code or reinstate L8490 for a suction suspension interface for prosthesis, Trade Name: Hypobaric Interface. According to the requestor, the Hypobaric Suspension System is a popular solution for suction suspension in the trans-femoral patient, especially those who are unable to use the traditional silicone liner for suspension. It is used to facilitate suction suspension for the prostheses of amputees.

Request #05.104
Harold Sears of Motion Control, Inc. submitted a request to create a new code to identify the Flexion Wrist feature of the Motion Control Electric Hand and the Motion Control Electric Terminal Device (ETD). According to the requester, the Flexion Wrist feature gives Motion Control's myoelectric terminal devices (MC Hand or ETD) the ability to

flex and extend beyond the standard position, so that the Terminal Device may be used in more functional positions and a much more natural way by the prosthesis wearer. The device is intended only for use by persons with limb loss who are using a myoelectric prosthesis. The Flexion Wrist feature adds an additional degree of freedom to the hand. It can be positioned in a neutral position, a flexed position (30º), and locked in any one of those positions while used in any activities. The lock allows the position to be maintained for load applied up to 50 lbs at the tip of the fingers in any direction. The Flexion Wrist may also be used by individuals with an electric wrist rotator without any loss of utility.

Request #05.105
Harold Sears of Motion Control, Inc. submitted a request to establish a code for the Water Resistant Protective Sleeve, for use with a myoelectric prosthesis. According to the requester, the Protective Sleeve is primarily used in conjunction with Motion Control's Water Resistant Electric Terminal Device (ETD) to aid in keeping the non-water resistant areas of the myoelectric prosthesis clean and free from dirt and moisture, though it can be used with any terminal device. It allows the amputee wearer to use a prosthesis in a much wider range of environments, thus making it suitable for use in environments that have previously been prohibitive to wearers of myoelectric prostheses.

Request #05.106
Harold Sears of Motion Control, Inc. submitted a request to establish a code for the Water Resistant feature of an Electric Terminal Device (ETD). According to the requester, the Water Resistant feature of the Motion Control Electric Terminal Device (ETD) allows the amputee wearer to use a prosthesis in a much wider range of environments. The water resistant housings are also impervious to dust and dirt, thus making it suitable for use in environments that have previously been prohibitive to wearers of myoelectric prostheses.

Request #05.107
Susan Treiber of Ossur North America/Generation II USA submitted a request to establish 2 "L" codes for Magnetorheologic (MR) Actuator (currently used on the Rheo Knee, a microprocessor-based knee, manufactured by Ossur). The applicant requests the following language: A) L58xx "Addition to lower extremity prosthesis, endoskeletal knee-shin system, single axis, magnetorheologic swing and stance phase control"; and B) L59xx "Addition to endoskeletal knee-shin system, magnetorheologic stance extension, dampening feature, with or without adjustability". According to the requester, the actuator is the part of the prosthetic knee that physically creates resistance for swing and stance phase control. The Magnetorheologic (MR) Actuator is the actuator on the Rheo Knee, Ossur's innovative microprocessor-based knee. The Rheo Knee contains a Magnetorheologic (MR) Actuator which utilizes Magnetorheologic fluid and magnetic fields to provide swing and/or stance phase control. The MR Actuator contains small iron particles suspended in oil and is a "zero-pressure" system. It produces no force to

control swing and/or stance phase control. Instead, resistance is created by magnetic fields which are generated as a result to the sensors. The magnetic field actually causes the magnetic particles to line up, thus thickening the MR fluid. The actuator has a stack of thin, steel rotary blades (discs) with fine gaps between the blades.

Request #05.108
Kaia Ann Halvorson of Hanger Prosthetics and Orthotics and Hanger Orthopedic Group Inc., submitted a request to establish a code for custom molded/designed total contact burn mask/orthosis also referred to as a Transparent Facial Orthosis TFO, Transparent Face Neck Orthosis TFNO, or Transparent Neck Orthosis TNO. According to the requester, TFOs, TFNOs, TNOs and custom molded burn masks are made from durable clear plastic materials that can withstand repeated use; material examples include surlyn or vicac. Patients typically wear these orthosis for 12-30 months with no negative performance or durability issues. Patients may use the same orthosis for the entire treatment regimen, however if there are anatomical changes that cannot be accommodated with the current orthosis a second orthosis may be indicated.

Request #05.109
Kathy Dodson of American Orthotic and Prosthetic Association submitted a request to establish a code for the "addition to Knee Ankle Foot Orthosis, articulation at ankle joint." According to the requester, the addition to a Knee Ankle Foot Orthosis (KAFO), allows free plantar and dorsiflexion motion at the ankle. This allows many clinical options for treating the patient's ankle foot pathologies when using a KAFO to address knee instability. Further description includes the application of components and modification to the ankle area of KAFO to allow motion at the ankle in the plantarflexion or dorsiflexion range of motion. The allowance of motion at the ankle can be valuable in several ways. Without this plantarflexion, the knee would be translated forward due to solid nature of the foot/ankle portion of the KAFO. This would significantly increase the risk of falls. Also dorsiflexion range allowance at the ankle can be beneficial to the flaccid paralytic, to maintain passive dorsiflexion range of motion which will contribute to the reduced risk of plantarflexion contractures.

Request #05.110 A+B
Kathy Dodson of American Orthotics & Prosthetics Association, submitted a request to establish a code for (**A**) Upper Extremity Prosthetic Glove Silicone, Production Glove; and (**B**) Upper Extremity Prosthetic Glove Silicone, Custom. According to the requester, these items are a prosthetic covering for upper extremity terminal devices fabricated from raw silicone materials. They are utilized on approximately one half of the upper extremity amputee population who are active wearers of a prosthesis, approximately 65% are production gloves and 35% are custom fabricated.

Request #05.111

Jason Bradshaw of Scott Orthotic Labs, Inc. submitted a request to establish a unique code for the Zero-G Suspension Unweighting Orthotic Walker. Following a National Panel decision based on prior request #04.267; the SADMERC assigned this product to existing code L4386 WALKING BOOT, NON-PNEUMATIC, WITH OR WITHOUT JOINTS, WITH OR WITHOUT INTERFACE MATERIAL, PRE-FABRICATED, INCLUDES FITTING AND ADJUSTMENT. The applicant claims the Zero-G Suspension Unweighting Orthotic Walker should be differentiated from other products coded in the L4386 category because this product provides suspension, unweights the foot and ankle, and relieves plantar surface pressure whereas a "standard walker" does not provide suspension. The Walker incorporates a supple but strong leather lacer calf corset with lace and Velcro closures. This design provides for a completely adjustable/total contact hydrostatic lift of the inverted cone shape of the calf. The rigid plastic rocker sole and malleable metal uprights provide a strong stable substructure in order to transfer the weight from the ground to the calf and not the foot and ankle. The unique design allows for repeatability in the donning process to insure proper unweighting every time it is fit. This also allows the doctor to easily check the patient at their regular office visits. The Zero-G has two main components; the Walker base, which includes the foot insure with ¼" Plastozote and 1" memory foam, donning pad, and protective foot cover. And the leather calf lacer which includes the laces, straps and one pair of SmartKnit Diabetic over the calf socks. These two components are sized according to measurements.

Request #05.112
Greg Huckert of Townsend Design submitted a request to modify the descriptors of existing codes L1843 KNEE ORTHOSIS, SINGLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT, MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT and L1844 KNEE ORTHOSIS, SINGLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT, MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, CUSTOM FABRICATED to include double upright knee braces. According to the requester, there are no specific base codes that describe double upright custom or prefabricated OA unloader type knee braces. The Townsend Reliever Series OA knee braces consist of double uprights and dual hinges, with thigh and calf bands. The knee joints will permit changes in flexion, extension, and varus/valgus alignment. These custom and prefabricated OA knee braces are designed to reduce load and maintain normal leg alignment for patient's requiring treatment for unicompartment OA of the knee joint. The knee braces provide medial-lateral support and rotation control, and also allow for adjustments to the corrective force applied by the brace. These braces are effective in reducing pain by decreasing the load on the compromised compartment. In addition to minimizing pain, the braces reduce wear and tear on the knee and slow down the progression of degeneration of the bony surfaces of the joint.

Request #05.113
Kathy Dodson of American Orthotic and Prosthetic Association submitted a request to establish a new "L" code with the following requested language: "Knee Ankle Foot Orthosis (KAFO), full plastic, with knee joint, multi-axis ankle, (Lively Orthosis or Equal), custom fabricated". According to the requester, this device is differentiated from other orthoses that cross the knee ankle and foot (KAFO's) by its design and componetry. Its most unique characteristic is its ankle joint, which permits movement in a saggital, transverse and coronal planes. It also embodies a knee joint component, which by utilizing one of the various knee joint additions, imparts specific range of motion control to the knee. Its body panels would consist of thermo-formable or thermosetting plastics and would be rigid so as to effectively transfer force across the knee and ankle joints. Finally, a strapping system is designed to effectively keep the orthosis in close contact with the extremity. According to the applicant, in 2005, the descriptor for L2038 was changed to read "without knee joint", and, since there are times when a knee joint is utilized, to manage both knee and ankle contractures, and a code is needed to describe a device provided with a knee joint.

Request #05.114
Kathy Dodson of American Orthotic and Prosthetic Association submitted a request to establish a new "L" code for Polycentric Knee Joint to replace L2435 ADDITION TO KNEE JOINT, POLYCENTRIC JOINT, EACH JOINT, which was discontinued 12/31/04. According to the requester, Polycentric Knee joints are used as the knee joints of orthoses that cross the anatomical knee joint (typically Knee Orthoses (KO) or Knee Ankle Foot Orthoses (KAFO)). The joints allow flexion and extension through a normal range of motion. The joints are actually added to the device as fabrication of the device occurs. The general term for polycentric actually describes several types of joint mechanisms developed, produced and marketed by multiple manufacturers and distributors. The term "polycentric" by its very nature implies "more than one center of rotation". This general description is further described by the functional breakdown of "bi-centric" joints. This means that they have two (2) centers of rotation about which motion occurs. Polycentric joints are indicated for any patient who uses a device where closely duplicating the relationship of the anatomical knee joint enhances the stability of the knee and where sheer or excessive pressures can put the patient at risk for further injury to knee joint, or to the skin tissues on the surface of the leg itself.

Request #05.115

Tuana Pryor of Bristol-Myers Squibb Medical Imaging has submitted a request to establish a code for perflutren lipid microsphere injectable suspension, Trade Name: Definity® and recommends the following language: INJECTION, ACTIVATED PERFLUTREN LIPID MICROSPHERE, PER 2ML. According to the requestor, Definity is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. The visualization of cardiac structures is necessary for a complete assessment of

the echocardiographic image. It is administered intravenously, with a typical dose being 1.3 mL. It is supplied sterile as a single use 2-mL clear glass vial.

Request #05.116
Lisa Holmes of AstraZeneca Pharmaceuticals, LP has submitted a request to revise code J7626 or to create a new HCPCS J code with the following requested language: "BUDESONIDE INHALATION SOLUTION, ADMINISTERED THROUGH DME, UNIT DOSE FORM, 0.25 TO 0.50MG NOT TO BE USED TO REPORT ANY SINGLE OR COMBINATION PHARMACY-COMPOUNDED BUDESONIDE PREPARATION", trade name: Pulmicort Respules. According to the requestor, Pulmicort Respules® is indicated for the maintenance treatment of asthma. It is a sterile suspension of a micronized form of budesonide that is specially formulated for inhalation through nebulization. It helps to control asthma by reducing the inflammation that often precipitates an asthma attach or bronchospasm. Improvement in asthma control following treatment can occur within 2 to 8 days of starting treatment, with a maximum benefit in a few weeks. It is the first and only anti-inflammatory corticosteroid formulated for inhalation using a compressed air driven jet nebulizer that is indicated for children between the ages of 12 months and 8 years. It is approved in two strengths: 0.25mg./2mL and 0.5mg./2mL.

Request #05.117
Joshua Ofman of Amgen USA submitted a request to establish a code palifermin, trade name: Kepivance™. Requested description: INJECTION, PALIFERMIN, PER 6.25 MG. According to the requester, Kepivance is a human keratinocyte growth factor (KGF) produced by recombinant DNA technology in Escherichia coli (E coli). Kepivance is a water-soluble, 140 amino acid protein with a molecular weight of 16.3 kilodaltons. It differs from endogenous human KGF in that the first 23 N-terminal amino acids have been deleted to improve protein stability. Kepivance is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support. The safety and efficacy of Kepivance™ have not been established in patients with non-hematologic malignancies. The recommended dosage of Kepivance is 60 mcg/kg/day, administered as an IV bolus injection for 3 consecutive days before and 3 consecutive days after myelotoxic therapy for a total of 6 doses.

Request #05.118
Krista Vihma of Lash Group submitted a request to establish a code for etonogestrel contraceptive implant, trade name: Implanon™. Applicant requests the following code description: Jxxxx ETONOGESTREL CONTRACEPTIVE IMPLANT, 68MG. According to the requester, Implanon is a single use, single-rod contraceptive implant that is inserted under the skin of the upper arm. It consists of a non-biodegradeable rod measuring 40 mm in length and 2 mm in diameter. Implanon is inserted just under the skin in the medial aspect of the upper arm 6-8 cm above the elbow crease in the overlying

groove between the biceps and triceps muscles. It is inserted by a trained medical professional with a specially designed applicator. Each Implanon rod contains ethylene vinylacetate copolymer core, containing 68mg of the synthetic progestin etonogestrel, surrounded by an EVA copolymer skin. The average hormone release rate is 30-40 micrograms per day. After insertion, the rod slowly releases a progestogenic hormone, etonogestrel which prevents the inhibition of ovulation and thickening of cervical mucosa. Implanon does not contain estrogen, making it suitable for women who do not tolerate or are contraindicated to estrogens. It is used for the prevention of pregnancy in women of reproductive age for up to 3 years.

Request #05.119
Ellen Wallis of CoTherix, Inc. submitted a request to establish a code for iloprost inhalation solution, trade name: Ventavis™, single use ampule. According to the requester, Ventavis is a prostacyclin solution that is administered via inhalation, 6-9 times daily through only the Prodose AAD system, a pulmonary drug delivery device. It is indicated for the treatment of pulmonary arterial hypertension in patients (PAH) with NYHA class III or IV symptoms. Ventavis vasodilates the pulmonary arterial bed leading to significant improvement of pulmonary artery pressure, pulmonary vascular resistance, cardiac output, and mixed venous oxygen saturation. Ventavis delivery is non-invasive; it provides direct delivery to the lungs; it avoids the systemic effects associated with invasive methods of drug delivery; there are no rebound effects associated with the withdrawal of drug; and it avoids significant morbidity/complications associated with the subcutaneous and central venous catheters required for delivery of the invasive prostacyclins. Ventavis is administered via inhalation through the Prodose, a breath-actuated pulmonary drug delivery device and the only device that has been specifically customized to deliver a consistent and accurate dose of Ventavis. The drug is supplied in a single-use ampule containing 2mL/20 mcg of Ventavis inhalation solution. The patient transfers the entire contents of one single-use ampule into the Prodose that administers the drug through the mouthpiece during the patient's normal inhaled breathing pattern.

Request #05.120
Ron Billingsley of Respironics, Inc. submitted a request assign a HCPCS code to the Prodose Adaptive Aerosol Delivery System and requests that the code descriptor state that the device is specifically for use with Ventavis. According to the requester, the Prodose AAD system represents a unique technology to deliver a predefined amount of aerosol to the patient's lungs. AAD was designed to minimize the variability of the delivered dose, to minimize the waste of aerosol to the environment and to improve the patients' adherence to their treatment and compliance with the user specification of the device. AAD systems adapt delivery of aerosol to the patient's breathing patterns, eliminating the greatest source of variability in drug delivery associated with conventional jet and ultrasonic nebulizers. The timing of the pulse of aerosol to be delivered to the patient is determined by the analysis of the breathing pattern. AAD systems analyze the pressure changes of the airflow of the first three breaths, to ascertain the correct starting point for aerosol delivery. It also provides the patient with feedback on how to effectively use the AAD system during the treatment, which improves

adherence to treatment and compliance with device. Prodose uses the AAD disc to control drug delivery. The Prodose system consists of a compressor connected to a self-powered handpiece fitted with a liquid crystal display.

Request #05.121
Terry O'Brien of Omron Healthcare, Inc. submitted a request to have the NE-U22 Micro-Air vibrating mesh nebulizer reclassified from under current HCPCS code E0574 ULTRASONIC/ELECTRONIC AEROSOL GENERATOR WITH SMALL VOLUME NEBULIZER to E0571 AEROSOL COMPRESSOR, BATTERY POWERED, FOR USE WITH SMALL VOLUME NEBULIZER. According to the requester, NE-U22 is a small volume electronic nebulizer that operates on 2 "AA" batteries and has an AC power option. It produces a breathable aerosol by breaking solution medications into small aerosol particles that can be inhaled into the lungs. The nebulization takes place by forcing medication from the medication bottle through a mesh plate containing 6,000 holes. Nebulized medication then passes from the top of the mesh through either a mouthpiece or mask to the user, which is then inhaled into the lungs. NE-U22 is used by any patient who suffers from respiratory conditions that require medications that are delivered to the lungs. NE-U22 provides relief of airway disease and can be used in any setting provided that the patient has access to their medication and device.

Request #05.122
Beth Guevara of Respironics, Inc. submitted a request to establish a separate code for a therapy data management system for positive airway pressure devices, trade name: Respironics SleepLink™ Modem System and Encore® Pro SmartCard® Technology. According to the requester, the SleepLink and SmartCard are used with continuous positive airway pressure (CPAP) devices and bi-level respiratory devices. In addition, the SleepLink can be used with XPOD® oximetry device to provide oxygen saturation data. Both products are use by patients who are diagnosed with obstructive sleep apnea that utilize CPAP and bi-level technology in the treatment of their condition. Compliance and event monitoring information associated with the use of these devices is essential to the effective treatment of sleep-related conditions. The SleepLink and SmartCard are two technologies that provide efficient ways to monitor sleep therapy compliance and event data by offering in-depth information for analysis. SmartCard is a removable data recorder card that is installed into the side of a compatible PAP device. It can then be downloaded for review by the patient's physician or homecare provider through the use of Encore Data Management Software. SleepLink is a data recorder system like the Smartcard with the addition of a modem device that allows home care providers to transmit data for review and interpretation by the treating physician. The SleepLink allows the option to download compliance data only or compliance data and oximetry information simultaneously.

Request #05.123
Martha Christian of the Princeton Reimbursement Group submitted a request to establish a code for auto or self-adjusting positive airway pressure devices (APAP), trade name:

AutoSet Spirit System. According to the requester, AutoSet Spirit is a flow-based auto-adjusting respiratory device used in the treatment of Obstructive Sleep Apnea. It employs sophisticated sensors and microprocessors not present in standard CPAP machines. The device's unique mode of action allows the device to respond to these various parameters: flow limitation, snoring, hypopnea, complete obstruction or any combination of the aforementioned breathing patterns. AutoSet's mode of action delivers varying levels of pressures based on the detected sleep disordered breathing events and may change pressure on a breath-to-breath basis. This device is only used when the patient has failed on a standard CPAP.

Request #05.124
Nicholas Macmillan of DeVilbiss submitted a request to establish 2 codes A) 1 code for the modem and B) 1 code for the subscription fee of an electronic positive airway pressure monitoring device, trade name: eCompliance. According to the requester, eCompliance is an electronic compliance tracking system that is comprised of three elements: smart track modem, internet processing software and PAP device (CPAP, bilevel or AutoAdjust). eCompliance is a system that electronically monitors a patient's PAP usage and automatically notifies those responsible for therapeutic management, i.e. physician, sleep technologist, home medical equipment provider, of low usage. The system works with standard CPAP, bilevel and auto-adjusting devices. Objective and quantitative parameters monitored include daily hours of use, on/off data and pressure. The PAP device is set up in a patient's home. The SMLink 300 is connected to the PAP device and to the patient's telephone line. SMLink quietly calls the DeVilbiss IPS server during the night and transmits the previous day's information. The call frequency is the first 7 days and every 3 days thereafter. Patient PAP information is available via the secure, password protected IPS server, 24/7.

Request #05.125
Steve Moore of Fisher & Paykel Healthcare, Inc. submitted a request to establish a code for a CPAP system with heated CPAP delivery tubing, trade name: HC604JHU Integrated Humidified CPAP with ThermoSmart Heated CPAP tubing. According to the requester, the HC604JHU Integrated Humidified CPAP is a CPAP device with an inbuilt heated humidifier. It utilizes a proprietary algorithm and an internal power supply to provide the power to run a heated breathing circuit known as 900HC522 ThermoStart heated CPAP delivery tubing. The HC604 and Thermosmart tubing combine to deliver positive airway pressure with optimal humidity, condensation free to CPAP patients. Thermosmart is used in the home for patients that require heated humidification with positive airway pressure therapy. This form of PAP is primarily prescribed to patients with Obstructive Sleep Apnea.

Request #05.126
Steve Moore of Fisher & Paykel submitted a request to establish a code for a heated humidification system, trade name: MR850 Heated Humidification System. According

to the requester, the MR850 heated humidification system is stand-alone "durable medical equipment" that consists of a heated humidifier and all of the necessary components required to deliver optimal humidity in a variety of applications. The MR850 is a new generation auto set dual servo controlled humidifier that offers invasive (trached) or noninvasive (mask or cannula) at the push of a button. In the invasive mode, the MR850 conditions gases to core temperature saturated and in the noninvasive mode, the MR850 conditions gases to match normal inspiratory levels. The MR850 is used for ventilation (invasive and noninvasive), respiratory assist (with and without back-up rate), positive airway pressure (noninvasive positive pressure ventilation), and continuous flow (humidified gas therapy and high flow oxygen therapy).

Request #05.127

Lance Matthews of CANADALEG Inc. submitted a request for a "L" code for a mobility rehabilitation device, Trade Name: IWALKFree. According to the requester, the IWALKFree is a rehabilitation device that can also be used as a temporary prosthetic. It replaces a missing lower leg or a lower leg that has been injured and is in need of rehabilitation. It allows weight to be transmitted through the flexed knee resulting in no weight being borne by the tibia, ankle, or foot. The device is made of a fiber reinforced injection molded knee tray with adjustable fitting positions that is attached to an extruded single piece aluminum shaft. Hypoallergenic foam is used on the knee tray, which allows bare skin and wounds to be attached directly to the tray. A three-point attachment system ensures stability. It is set off center, with rounded rubber foot, which replicates normal walking motion.

Request #05.128

Joseph Lewarski of Inogen, Inc. submitted a request to establish a code for an oxygen concentrator, trade name: Inogen One Oxygen Concentrator. According to the requester, the Inogen One is a small, lightweight oxygen concentrator capable of fulfilling low flow prescriptions for oxygen while functioning as both a stationary and portable oxygen delivery device. It produces more then 90% pure oxygen for low flow oxygen therapy applications. Inogen One works on the principles of pressure-swing-adsorption, common to all oxygen concentrators. This oxygen production method draws and filters ambient air from the room by passing it through a filter system composed of a superior molecular sieve material. The sieve separates the oxygen from the nitrogen in the air, accumulates it and then pressurizes it in a reservoir. The oxygen-enriched gas is supplied to the patient via a standard nasal cannula in accordance with a physician prescription. Inogen One provides the prescribed oxygen to the patient at an equivalent rate of 1 to 5 liters per minute in increments of 0.5 liters per minute for a total of nine settings. Inogen is used by patients who are prescribed long term oxygen therapy (LTOT) outside of the acute care environment. Language proposed by applicant: EXXXX PORTABLE OXYGEN CONCENTRATOR USED AS A PORTABLE OXYGEN DELIVERY DEVICE, WEIGHING LESS THAN 10 POUNDS, CAPABLE OF DELIVERING 85% OR GREATER OXYGEN AND PROVIDING AT LEAST 2 HOURS OF REMOTE PORTABILITY AT A 2 LPM PRESCRIPTION EQUIVALENCY; INCLUDES

CONCENTRATOR, CANNULA, TUBING AND AC/DC POWER CORD AND ADAPTER

Request #05.129A+B

James Boswell of King & Spalding LLP submitted a request to A) either suggest that the Statistical Analysis Durable Medical Equipment Regional Carriers (SADMERC) reassign the Nasal Pap Freestyle Cushions from A7033 REPLACEMENT PILLOWS FOR NASAL APPLICATION DEVICE, PAIR to A7032 REPLACEMENT CUSHION FOR NASAL APPLICATION DEVICE, EACH; or establish a new code for the Nasal Pap freestyle Cushions and B) to either suggest that the SADMERC reassign the Nasal-Aire II Cushion from A9999 to A7032 or to establish a new code for the Nasal-Aire II Cushion. According to the requester, Nasal Pap cushions are rough cylindrical cushions made with a soft medical grade silicone. These cushions are used in conjunction with a CPAP device for the treatment of patients with obstructive sleep apnea and related disorders. A pair of the Nasal Pap cushions is inserted into each nasal cavity and connected to tubing and a swivel connection and then to the CPAP positive air pressure machine. Nasal Pap cushions channel air with a laminar flow from the CPAP machine to the patient's nose, providing patients with breathing assistance. Nasal Aire II consists of a connected pair of cylindrical nasal inserts to be used in conjunction with a CPAP device for the treatment of patients with obstructive sleep apnea and related disorders. The cushion's nasal inserts are inserted into each nasal cavity and forms an air seal with each nasal cavity. Nasal Aire II cushion channels air with a luminar flow from the CPAP machine to the patient's nose, providing breathing assistance.

Request #05.130

James Koeneman of Kinetic Muscles, Inc. submitted a request to establish a code for a repetitive active motion device, trade name: Hand Mentor. According to the requester, Hand Mentor is a device designed primarily for rehabilitation therapy for those having suffered a stroke. This device is primarily used for Active-Assist stroke therapy where the patient is encouraged to move as much as possible and then the device completes the motion for the patient. An artificial pneumatic muscle provides the coordinated motion. In addition, the device measures the electrical activity of selected muscle groups through surface electromyographic electrodes and the resistance of spastic muscles and feeds back this information to the patient to encourage maximum effort.

Request #05.131

David Hintzman of Bodypoint, Inc. submitted a request to establish a code for a dynamic pelvic stabilization device, trade name: Bodypoint Hip Grip. According to the requester, Bodypoint is a pelvic stabilization device equipped with variable resistance springs that assists the wheelchair user to maintain pelvic stability while allowing functional pelvic movements. Hip Grip incorporates rear, front, and side support of the pelvis in an adjustable unit, which allows the pelvis to pivot forward about the hip joint within a specified range. It reduces undesired pelvic movement and provides variable resistance to bring the pelvis back into its neutral posture after allowing movement. The

combination of pelvic positioning and dynamic pelvic movement improves functional activities and enhances sitting posture. Bodypoint is used primarily by those patients with cerebral palsy and spinal cord injury. The pivot mechanism of Bodypoint incorporates an elastic resistance band that allows forward pelvic movement within range depending on the person's flexibility, balance and feedback. The quick release wheelchair attachment hardware combination assures the greatest compatibility with a wide range of wheelchairs and the ability to remove it for folding the wheelchair when necessary.

Request #05.132A
Jonathan Cabral of Bionicare Medical Technologies, Inc. submitted a request to establish a code for a knee signal applicator used with the BioniCare Stimulator, Model BIO-1000. According to the requester, the knee signal applicator is a "noninvasive arthritis treatment device that is worn outside of the body on the joint requiring treatment". BioniCare Signal Generator delivers a specific electrical output to contact elements that are held in place by this knee signal applicator system that accurately positions and applies a special treatment contact element to the surface of the knee and a special return contact element to the surface of the thigh. Bionicare's knee signal applicator is worn on the knee when an adjunctive therapy is used to reduce the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation. The knee signal applicator is applied using a fastener system of Velcro materials, a support belt, and suspension strap. Both right and left knee applicators and support belts are manufactured in three sizes, small, medium, and large. The knee signal applicator is designed for use eight to ten hours daily for periods up to two years. It can survive up to 350 hand-washing cycles. Code description recommended by applicant: E07XX SIGNAL APPLICATOR DEVICE, KNEE; FOR USE WITH ARTHRITIS TREATMENT DEVICE

Request #05.132B
Jonathan Cabral of Bionicare Medical Technologies, Inc. submitted a request to establish a code for a replacement battery use with the BioniCare Stimulator, Model BIO-1000. According to the requester, the battery is part of BioniCare's Stimulator, Model BIO-1000 System, which is a noninvasive arthritis treatment device that is worn outside of the body on the joint requiring treatment. The rechargeable battery is required for continued operation of the electronic signal generator. Battery life is dependent on patient use patterns. Under normal use conditions, it is anticipated that a replacement battery will be required after 12 months. Code description recommended by applicant: A46XX REPLACEMENT BATTERY FOR ARTHRITIS TREATMENT DEVICE ELECTRONIC SIGNAL GENERATOR, EACH

Request #05.132C
Jonathan Cabral of Bionicare Medical Technologies, Inc. submitted a request to establish a code for replacement supplies used with the BioniCare Stimulator, Model BIO-1000.

According to the requester, the replacement supplies are part of the BioniCare Stimulator Model BIO-1000 that is worn outside of the body on the joint requiring treatment. This code request is specific to report a kit of replacement supplies, including 2 contact elements/electrodes and 6 (8.5oz) supplementary gel tubes. The quantity of supplies is expected to last 2-3 months under typical product use conditions for one signal applicator. A second set of supplies would be required if a patient were using two signal applicators. Code description recommended by applicant: A4xxx ARTHRITIS TREATMENT DEVICE SUPPLY KIT, EACH.

Request #05.132D
Jonathan Cabral of Bionicare Medical Technologies, Inc. has submitted a request to establish a code for an arthritis treatment device, Trade Name: BioniCare® Stimulator, Model BIO-1000™. According to the requestor, the BioniCare Stimulator, Model BIO-1000™ is a non-invasive arthritis treatment device that is worn outside of the body on the joint requiring treatment. It is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation and an adjunctive therapy in reducing the level of pain and stiffness from rheumatoid arthritis of the hand. The device is worn for 8 +/- 2 hours every day, usually at night but can be worn during the day. Clinical experience indicates a range of use from one to 51 months. The average length of use in a long term study was 11 months. Description recommended by applicant: E07xx ARTHRITIS TREATMENT DEVICE, ELECTRICAL, NONINVASIVE.

Request #05.133
Patty Curoe of Medtronic Diabetes submitted a request to establish a code for The Pathway™ Program, separately purchased software that allows patients to upgrade their insulin pumps, rather than purchasing an entirely new pump. Applicant suggests the following language for the requested new code: Exxxx SOFTWARE UPGRADE, EXTERNAL AMBULATORY INFUSION PUMP. According to the requester, Paradigm is software that is used to upgrade existing insulin pumps. This accelerates patient access to ongoing clinical advancements, without incurring repeated pump replacement costs or long delays in technology advances during pump warranty periods. Pathway can be used to update earlier versions of insulin pumps to obtain the calculator feature. In addition, other innovations such as radio frequency transmitted blood glucose values from meters to pumps are available without incurring the full costs of a replacement pump. Future advances that are expected to be a part of Pathway include an upgrade to accept and display real time glucose readings from an external glucose sensor and transmitter.

Request #05.134
David Boninger of Three Rivers submitted a request to establish a code for wheelchair propulsion and braking assembly, trade name: Natural-Fit™. According to the requester,

Natural Fit is a wheelchair propulsion and braking assembly ergonomically designed to fit the hand and reduce stress on the hands, wrists, and arms when propelling a manual wheelchair, thereby treating the pain associated with Carpal Tunnel Syndrome (CTS). The Natural Fit is an assembly because it has two separately coated components, a smooth oval surface for the palm of the hand and a higher friction contoured slot for the thumb. The assembly of these two components is designed to create an ergonomic grip for the hand and to provide separate surfaces for propulsion and braking. The contoured trough provides a surface area between the rim and tire to increase the contact area for the thumb to apply propulsion forces. By adding the trough, the gap between the tire and standard handrims is eliminated which enhances safety (e.g., fingers can no longer get caught in the gap). The ergonomic grip provided by the combination of the contoured trough and the oval component of the Natural Fit reduces finger tip loading, pinch gripping, and excessive activation of the finger flexors during wheelchair propulsion.

Request #05.135
Robert Fulton III of Glance Wheels, LLC submitted a request to establish a unique code to differentiate rear wheels for manual wheelchairs that are maintenance free, extended life, high durability from other rear wheels currently coded at K0069, K0070 or K0108. According to the applicant, Glance wheels are no maintenance, high durability, high strength aircraft quality aluminum rear wheels. These wheels are intended for long term and active use. Glance wheels are intended to never be replaced and can have an extended and continuous "life". Thus Glance Wheels are resistant to usual "wear and tear" common with active disabled users of manual wheelchairs. These wheels do not require "spoke tuning" or "truing" of the wheel rim. Glance wheels are used by paraplegics, quadriplegics, amputees and other individuals using a manual wheelchair for over 4 hours per day with a continued wheelchair use to exceed one year. Current codes do not specify a high endurance, long life, no maintenance product for active users of manual wheelchairs.

Request #05.136
Greg Howard of Independence Technology, LLC submitted a request to establish a code for a mobility system, trade name: Independence iBot 3000 Mobility System. According to the requester, iBot is a sophisticated mobility system with patented iBalance technology enabling users to climb and descend stairs, navigate surfaces, ascend curbs and balance the seat user at a "standing" eye-level height. iBot is an integrated combination of mechanical, electronic, sensor, and software components that is customized to the user's size, weight and center of gravity. The iBalance technology is comprised of six solid-state gyroscopes, three tilt sensors, three computer processor systems and multiple sensors. This technology is integrated with a cluster of two, interconnected, 12-inch wheels on each side of the device as well as two smaller caster wheels in the front of the device. The device automatically adjusts wheel and/or frame position in reaction to changes in pitch, wheel velocity, wheel position, seat height and other parameters based on a complex series of computerized sensors and software algorithms. iBot is powered by two, 72-volt rechargeable nickel-cadium batteries that can power the device all day on a single charge depending on usage.

Request #05.137
Brad Selman of Coloplast A/S submitted a request to establish a code to distinguish hydrophilic intermittent urinary catheters from catheters made of other materials. According to the requester, SpeediCath® is a sterile, single use, hydrophilic-coated intermittent catheter that is pre-lubricated in sterile saline solution. The SpeediCath® hydrophilic coating, which consists of sterile water, is chemically bonded to the catheter, ensuring the coating is consistent and remains on the catheter throughout catheterization. The catheter is always optimally hydrated; consequently it is extremely slippery, extremely comfortable, and may cause less trauma to the urethral tissue than other catheters. SpeediCath® is designed for single use and must be discarded after one use. Because SpeediCath® is packaged in a sterile saline solution, and is pre-lubricated, users do not have to find water or squeeze a sachet to release water into the package, or apply a secondary lubricant. The applicant claims that "it may be medially necessary to use SpeediCath®, rather than a conventional catheter (i.e., a catheter that requires application of a lubricant) in a situation where a patient is susceptible to urinary tract infections, has a history of urethral trauma or infection, or requires sterile catheterization for some other reason". The applicant also claims that "Hydrophilic and conventional catheters are not functionally equivalent;" that "Hydrophilic technology may offer a safer, more hygienic form of intermittent catheterization and is appropriate for certain patients"; and suggests that access to Hydrophilic catheters is limited in the absence of a unique code to isolate catheters made with hydrophilic materials. This applicant distinguishes the SpeediCath from other hydrophilic catheters based on prelubrication without the need to immerse in water prior to use.

Request #05.138
Grant Bagley of Arnold & Porter LLP submitted a request to establish 3 new codes for hydrophilic single use urinary catheter, Trade Names: LoFric® Plus, LoFric® Cath-Kit™, LoFric® Ready-Kit, and LoFric® H20 (collectively, LoFric® Catheters(s)) and revise 3 existing codes A4351, A4352 and A4353. According to the requester, hydrophilic catheters such as the LoFric® Catheter employ a multi-layer construction. A LoFric® Catheter (except LoFric® Plus) has a core of medical-grade polyvinyl chloride (PVC) and an outermost layer of polyvinylpyrrolidone (PVP) and sodium chloride (NaC1). This outer PVP/NaC1 layer is integral to the catheter and covers all external catheter surfaces that contact the urinary tract. The PVP/NaC1 attracts a layer of water that uniformly adheres to all external catheter surfaces. This bound water makes the catheter extremely slippery, allowing the catheter to move in the urinary tract with minimal friction and abrasion. The requester claims that there are "functional, chemical, physical technological and cost differences between hydrophilic and conventional catheters; differences in instructions for use; that the lack of unique codes describing hydrophilic catheters limits insurers' ability to track, process claims for and pay adequately for hydrophilic catheters and therefore limits patient access. Based on these claims, the requester suggests the addition of 3 new codes to describe hydrophilic

catheters and insertion supplies; and the revision of 3 existing codes (A4351-A4353) as follows, (where underlined text is added and struck through text is deleted):

1) A4351 INTERMITTENT URINARY CATHETER; STRAIGHT TIP, WITH OR WITHOUT COATING (TEFLON, SILICONE, OR SILICONE ELASTOMER, ~~OR HYDROPHILIC, ETC.~~)
2) A4352 INTERMITTENT URINARY CATHETER; COUDE (CURVED) TIP, WITH OR WITHOUT COATING (TEFLON, SILICONE, OR SILICONE ELASTOMER, ~~OR HYDROPHILIC, ETC.~~)
3) A4353 INTERMITTENT URINARY CATHETER, CONVENTIONAL WITH INSERTION SUPPLIES

Request the following "A" codes be established:
1) Axxxx INTERMITTENT URINARY CATHETER; STRAIGHT TIP, HYDROPHILIC
2) Axxxx INTERMITTENT URINARY CATHETER; COUDE (CURVED) TIP, HYDROPHILIC
3) Axxxx INTERMITTENT URINARY CATHETER, HYDROPHILIC, WITH INSERTION SUPPLIES

Request #05.139
Clarke Scherff of the Mentor Corporation has submitted a request to 1) modify existing codes A4351 and A4352, removing the reference to hydrophilic catheters and 2) create new codes for straight tip and coude (curved) tip hydrophilic catheters.
According to the requestor, the Self Cath® is designed for single use, intermittent urethral urinary self-catheterization. The low-friction hydrophilic surface activates immediately upon exposure to water for fast, clean lubrication and maximum ease of use. To facilitate catheterization, the Self Cath® Plus offers an uncoated GripZone™ area. It is flexible, has smooth fire polished eyelets and is made of medical grade polyvinyl chloride (PVC). The applicant claims that hydrophilic catheters are not functionally equivalent to catheters made with other materials, and provide improved clinical outcomes, and therefore they are fundamentally different from other catheters coded at A4351 and A4352. The applicant also claims that patient access is limited "due to low reimbursement which is a result of current HCPCS categorization"; and suggest that there is a National Medicaid program operating need to isolate hydrophilic catheters from catheters made with other materials.

Request #05.140
Randall Carson of Tyco Healthcare Group LP submitted a request to establish a specific code to describe time-released silver coating for the foley catheter, trade name: Dover Silver Foley Catheter™. According to the requester: 1) existing codes do not describe antimicrobial coatings, specifically silver; 2) this is a new science used to reduce the incidence of nosocomial infections; 3) reimbursement under existing codes is inadequate to cover the cost of this product. According to the requester, the Dover catheter is coated

with a lubricious (hydrogel material) hydrophilic topcoat containing an inorganic silver ion-releasing polymer. This coating is on the outer and inner catheter surfaces as well as on the balloon. The hydrogel coating acts as a delivery system by utilizing molecular particles to store and release silver ions throughout a 30-day period. The catheter is designed with two lumens; a drainage lumen and an inflation lumen. A round, molded, reinforced silicone tip, finishes the distal end of the catheter. Two drain eyes on opposing sides of the catheter, contiguous with the drain lumen, are located at the tip of the catheter, just distal to the retention balloon. The smooth balloon to shaft transition reduces insertion trauma. This balloon is inflated with sterile water through a syringe activated spring-loaded check valve and serves to retain the catheter in the bladder.

Request #05.141
Celeste Bonham of Uro Concepts Inc. has submitted a request to establish a code for a urine collection bag, Trade Name: Better Pant. According to the requestor, this item is an undergarment that holds the urinary collection bag in place on the user's leg without the need of leg straps. It is designed to be used with most urinary collection systems using 500ml or 1000ml bags. It contains an internal pouch that conceals and securely holds the urinary collection bag in place without leg straps.

Request #05.142
Michele Federico of Health Care Excel has submitted a request to establish a code for an ostomy clamp, Trade Name: Ostomy Clamp. According to the requestor, an ostomy clamp is a closure accessory used to prevent the unwanted spillage of an open-ended ostomy bag. They are supplied with open-ended ostomy bags and additional clamps may be purchased separately.

Request #05.143
Deanna Eaves of Hollister Incorporated has submitted a request to establish an "A" code and suggests the following language: "ostomy skin barrier, solid, 4x4 inches or equivalent, extended wear, with built-in convexity", Trade Name: ADAPT Convex Barrier Rings. According to the requestor, ADAPT Convex Barrier Rings are circular convex barriers made from an extended wear barrier material that will stand up to corrosive discharge. They are designed to protect the peristomal skin from contact and potential breakdown from corrosive discharge. They are available in three inner diameters: 20 mm, 30 mm, and 40 mm. The rings are designed to provide the end-user or clinician with the ability to develop customized convexity, which may improve the skin protection and wear time for the individual with the ostomy.

Request #05.144 A
Randall R. Carson of Tyco Healthcare Group LP has submitted a request to establish a code for enteral feeding pumps which have two separate interfaces functioning on two separate operation systems, Trade Name: Kangaroo® EntriFlush™ Enteral Feeding

Pump and Kangaroo® EPump™ Enteral Feeding Pump. According to the requester, these pumps are two-way or dual pumps that can separately provide enteral formula, and hydration. There are two different interfaces on one pump, which allow you to connect two bags at one time and set different infusion parameters for each. The pump mechanisms are rotary peristaltic as existing pumps, however there are separate operating systems that allow you to set separate infusion rates for the formula, and the hydration.

Request #05.144 B
Randall Carson of Tyco Healthcare Group LP has submitted a request to delete existing kit codes B4035 and B4036 and create a new series of codes to separately identify all kit supplies. According to the requestor, the current codes describe and are priced for one set (one bag and one tubing) for standard pumps, and do not describe a pump set required for dual flow pumps. Both of the existing code descriptors state "supply kit; per day" and only one unit of service can be billed for any one day. The requestor is asking for a series specific codes that will describe actual supplies used for enteral feeding, instead of using the terminology "kits". The list of supplies that codes would need to be established for are:

- Piercing spike pump set with 100ml water bag (dual flow set)
- 1000ml bag/pump set with 1000ml water bag (dual flow set)
- "Y" pump set with in line "Y" adaptor and piercing spike
- "Y" pump set with line "Y" adaptor and bag
- Top fill rigid container pump set – 500ml
- Top fill rigid container pump set – 1000ml
- 1000ml anti-free flow pump set
- 500ml anti-free flow pump set
- Screw cap pump set for rigid containers
- Top fill bag pump set – 500ml
- Top fill bag pump set – 1000ml
- Proximal spike pump set
- Pump set tubing extension
- Y-site extension set
- 1000 feed pump set with integrated flush bag
- 1000ml gravity bag
- Large bore gravity set
- Gravity feeding set with piercing pin
- Gravity feeding set with screw-on top
- Re-Certification Pump Set (#776150, ePump only)
- These items would also need duplicate codes for DEHP-free

Request #05.145
Mary Erslon, RN, MSN, of Tyco Healthcare/Nellcor Puritan Benefit has submitted a request to establish a code for a specialized/custom-fabricated tracheostomy tube, Trade Name: Shiley®. According to the requestor, Shiley specialized/custom tracheostomy

tubes are custom fabricated artificial airways that are constructed of medical grade materials. The applicant claims that they are custom fabricated for specialized length, curvature, fenestration, and cuffs for difficult to fit patients whose needs cannot be met with a standard tracheostomy tube. Specific airway requirements are measured by the patient's physician and submitted to Shiley for fabrication of a specialized/customized tracheostomy tube on an as-ordered basis. Tracheostomy tubes are artificial airways inserted into the trachea to relieve a breathing obstruction.

Request #05.146
Michelle Ford, of Helix Medical dba, InHealth Technologies, has submitted a request to change the verbiage of existing code A4364, and a request to establish a new code for a hypoallergenic adhesive, Trade Name: Blom-Singer Silicone Adhesive. Current A4364 verbiage: ADHESIVE, LIQUID OR EQUAL, ANY TYPE, PER OZ. Requested verbiage: "Adhesive, liquid or equal, for use near or around airways but not for inhalation/ingestion, per oz". Suggested language for requested new code: "Adhesive, liquid or equal, hypoallergenic, for use with tracheostomy, per oz". According to the requestor, Blom-Singer Silicone Adhesive is used to safely attach adhesive foam and tape discs to the skin. The adhesive ensures a tight seal to prevent air leaks, and leakage of mucous and must be applied daily or multiple times daily. It is intended for use by laryngectomees who have undergone surgical removal of their voice box/larynx and have undergone a tracheoesophageal puncture (TEP) for voice restoration. Currently, A4364 is used to describe the product; however it states "any type". The requestor feels that the adhesives used to create and price this code were developed for colostomies, ileostomies, or urinary stomas and their ingredients did not have to be tested/safe for inhalation. The requestor claims that the general description of the code may also confuse suppliers and they may offer an adhesive product to a tracheostomy patient that is not safe for them to use.

Request #05.147
Michelle Ford of Helix Medical dba, InHealth Technologies has submitted a request to delete A7506 ADHESIVE DISC FOR USE IN A HEAT AND MOISTURE EXCHANGE SYSTEM AND/OR WITH TRACHEOSTOMA VALVE, ANY TYPE, EACH and create two new codes to separately identify two types of adhesive discs (paper and foam). According to the requestor, the code that is currently used to describe this product, A7506, does not provide sufficient reimbursement as it is priced for the paper tape discs only, and not for the foam tape discs. The requested language for the new codes is: **AXXXX** Adhesive foam tape disc, for use in heat and moisture exchange system and/or with a tracheostoma valve, each. **AXXXX** Adhesive paper tape disc, for use in a heat and moisture exchange system and/or with a tracheostoma valve, each.

Request #05.148
Michelle Ford of InHealth Technologies has submitted a request to discontinue A7503 FILTER HOLDER OR FILTER CAP, REUSABLE, FOR USE IN A

TRACHEOSTOMA HEAT AND MOISTURE EXCHANGE SYSTEM, EACH, and to establish three new codes. Requested language is as follows:
AXXXX Filter cap, reusable up to one month, for use in a tracheostoma heat and moisture exchange system, each
AXXXX Filter cap, reusable for six months or longer, for use in a tracheostoma heat and moisture exchange system, each
AXXXX Filter holder, nonintegrated, reusable, for use in a tracheostoma heat and moisture exchange system, each
According to the requestor, there is a difference in the length of durability of the products grouped under A7503. Some of the caps can only be used for one month, whereas some of the caps can be used for up to one year. This difference in material and durability also results in a difference in cost. The requestor claims that code A7503 does not provide sufficient reimbursement as it is priced for the one-month disposable caps only, and not a filter holder or cap that can be used up to a year. The requester also claims that A7507 FILTER HOLDER AND INTEGRATED FILTER WITHOUT ADHESIVE, FOR USE IN A TRACHEOSTOMA HEAT AND MOISTURE EXCHANGE SYSTEM, EACH describes a one-time use only filter and requests a new code to identify a non-integrated filter holder which serves as a combined filter and cap, and is expected to last 8-12 months.

Request #05.149
Michelle Ford of InHealth Technologies has submitted a request to modify the HCPCS code set to differentiate between low pressure and duckbill style voice prostheses. Applicant suggests revising the verbiage of L8507 TRACHEO-ESOPHAGEAL VOICE PROSTHESIS, PATIENT INSERTED, ANY TYPE, EACH to instead read: “Tracheo-esophageal voice prosthesis, patient inserted, duckbill, each”, and requests a new code for low-pressure voice prosthesis, requested language: LXXXX “Tracheo-esophageal voice prosthesis, patient inserted, low-pressure, each”. According to the requestor, L8507 currently does not differentiate between the low pressure and duckbill style of prosthesis. The low pressure style is indicated for patients with insufficient air pressure to open the valve of patients whose esophagus is too narrow to accommodate the 8mm duckbill tip. The duckbill style was introduced in 1979, and the low pressure style has been on the market since the early 1980’s.

Attachment #05.150
Frederick Cahn of BioMedical Strategies LLC submitted a request to establish a unique code for multiple sizes of Collagen Glycosaminoglycan Bilayer Matrix (CGBM), Trade Names: Integra Dermal Regeneration Template, Integra Bilayer Matrix Wound Dressing. According to the requester, CGBM is a bilayer system comprising a dermal replacement layer and a temporary epidermal substitute layer. The dermal replacement layer is a porous matrix of fibers consisting of purified undenatured bovine collagen and chondroitin-6-sulfate with an average pore size between 70 and 200 µm and a void volume greater than 99%. The matrix is cross linked with aqueous glutaraldehyde at acetic pH. The temporary epidermal substitute layer is made of silicone 200 to 300 µm

thick and it firmly adheres to the dermal replacement layer. According to the requester C9206 is used for HOPPS. The applicant requests a unique code for use in physician's offices and by private insurers. The applicant states that existing code J7343 DERMAL AND EPIDERMAL, TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER does not describe the products that are the subject of this request because the codes describe dermal and epidermal tissue, whereas CGBM does not contain dermal or epidermal tissue. The applicant also claims that identifying the amount used based on "per square cm" "will under compensate users of smaller sizes". The product is available in 4 sizes: 2x2, 4x5, 4x10, and 8x10. The applicant suggests the assignment of a unit of "25 square centimeters" to the requested new code to be consistent with the unit of 25 square centimeters associated with CPT codes 15342 and 15343.

Attachment #05.151
William Hanson of Liberating Technologies, Inc. submitted a request to establish a code for protective silicone semi-custom outer leg cover, Trade Name: Skinergy. According to the requester, the protective outer silicone leg cover is applied to the outer covering of the trans-tibial prostheses by a prosthetic technician. Skinergy acts as a protective barrier for the interior components. With over 25% stretch qualities the product is not limited to certain interior components and can accommodate for instance feet and ankle systems that possess a range of movement. The product technology was derived from prosthetic silicone gloves for upper extremity hands. According to the applicant, the silicone outer leg cover differs from other products currently coded at L5962 ADDITION, ENDOSKELETAL SYSTEM, BELOW KNEE, FLEXIBLE PROTECTIVE OUTER SURFACE COVERING SYSTEM in the following ways: 1) the silicone product is more elastic and usable for more types of feet and ankle systems, including adjustable height ankles and high-activity prosthetic feet; 2) silicone is more stain resistant (and therefore would need to be replaced less often than PVC products); 3) the manufacturing process and raw materials are more costly for silicone than for PVC products, therefore existing reimbursement is inadequate.

Attachment #05.152
Sajini Thomas of Wright Medical Technology, Inc. submitted as request to establish a code for Micronized Acellular Soft-Tissue Scaffold, Trade Name: GRAFTJACKET® XPRESS Flowable Soft-Tissue Scaffold. According to the requester, this product is a micronized (finely ground) decellularized soft tissue scaffold indicated for the repair or replacement of damaged or inadequate integumental tissue, specifically deep, dermal wounds that exhibit tunneling, and extension from the wound base that may extend deep into the tendon and bone. It is processed and regulated in accordance with the FDA's requirements for the procurement and processing of banked human tissues (CFR Title 21, Part 1270 and 1271) and standards and guidelines of the AATB. The GRAFTJACKET® XPRESS is a soft tissue graft (reconstituted as a "gel"), which is comprised solely of human dermal tissue, including its native protein and collagen structure and essential

biochemical composition. The re-hydrated skin substitute scaffold is placed into the tunnels or tracts and produces the same or superior clinical outcomes with a minimally invasive procedure. The applicant claims that C9222 DECELLULARIZED SOFT TISSUE SCAFFOLD, PER 1 CC was established by CMS in 2005 for use in HOPPS, and that the sheet form of the product was assigned to J7344 DERMAL TISSUE, OF HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER in 2005. The applicant requests a J code for use in the physician office and ASC settings to identify the syringe-delivered form of this product. The applicant suggests the following language for the requested code: "Acellular soft-tissue scaffold gel, per 1 cc". The product is supplied in powder form as part of a kit that includes: 2cc volume of GRAFTJACKET® EXPRESS powder packaged 5cc syringe; 3cc syringe for rehydration; 21 G needle, 19G OPTIVA® catheter; and syringe connector.

Attachment #05.153
Lisa Colleran of LifeCell Corporation submitted a request to establish a series of 6 codes to distinguish varying thicknesses of Decellularized human tissue; human allogeneic skin; acellular tissue; allograft, Trade Name: AlloDerm® Regenerative Tissue Matrix. This is a request to replace existing C9221 ACELLULAR DERMAL TISSUE MATRIX, PER 16CM2 and J7344 DERMAL TISSUE, OF HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SWUARE CENTIMETER with a series of 6 codes, distinguished by product thickness and procedure, (graftable meshed; gaftable non-meshed; thin, medium, thick and ultra-thick). The applicant suggests the following language for the requested 6 codes: "Dermal tissue of human origin with or without other bioengineered or processed elements, without metabolically active elements, *by thickness*, per square centimeter". The requester claims that a series of codes is needed to account for different procedures, (implant and/or graft); thickness, and price). According to the requester, AlloDerm® is a regenerative tissue matrix. AlloDerm® acellular dermal graft is a human donor-derived single layer decellularized dermal sheet product for the repair or replacement of human tissue that is freeze dried before packaging. AlloDerm® is used in various procedures for the replacement or repair of damaged or inadequate integumental tissue including closing complicated ventral/incisional hernias, breast reconstruction, and open wound repairs. The tissue derived component is comprised of native human dermal architecture, consisting of about 70-85% collagen (mainly type 1 w/additional collagen type III and IV components), less than 2% each of the chondroitin sulfate and hyaluronic acid glycosaminoglycans, and up to 10% elastin.

Attachment #05.154
Kathleen Schaum of Kathleen Schaum & Associates, Inc. submitted a request to establish a code for acellular porcine-derived, small intestine submucosa products, trade names: OASIS® Wound Matrix and OASIS® Burn Matrix. The applicant requests a new J-code, to differentiate acellular, procine-derived, small intestine submucosa products from

already existing J-codes assigned to dermal and epidermal tissues of human and non-human origin. Oasis is biologically derived, extracellular matrix-based wound care products, translucent and off-white in color. They are obtained from the small intestinal submucosa (SIS) layer of the domestic pig. The isolated submucosa is chemically cleaned, decellularized, freeze-dried, and terminally sterilized. According to the applicant, existing codes (J7340-J7344) do not accurately describe this product for the following reasons: 1) this product is acellular and is not dermal or epidermal; 2) this product is of non-human origin; 3) this product contains bioactive components, however, according to the applicant, "it is not with/without metabolically active elements". The applicant suggests the following language for the requested code: "Acellular submucosal tissue of non-human origin (e.g. porcine), with bioactive components, per square centimeter".

Attachment #05.155
Marc Swartz of Dr. Len's Medical Products, LLC submitted a request to establish a code for Abrams Wound Care Bandage with 8.5% Silver Sodium Hydrogen Zirconium Phosphate. According to the requester, this wound care bandage is a tri-layer rectangle shaped hydrophilic foam composed of a ¼" layer of foam with a 2lb deflection laminated to a second piece being ½" with a 1lb deflection, followed by a third layer of foam which is one 1/8" thick. The third layer of foam is impregnated with a 8.5% silver sodium hydrogen zirconium phosphate with 1% of the total weight as silver. The applicant makes the following claims: The product was lab tested and proven effective for up to seven days warding off infection. The foam is able to stimulate and enhance the micro circulation to the site. The enhancement of microcirculation in the capillary bed results in increase capillary blood flow to the site. This increased flow results in an expedited time to closure of a wound stemming from the increased nourishment to the site of increased blood flow. The site heals from the inside out minimizing scaring while providing the site of treatment a warm, moist environment. The foam is able to absorb excessive wound exudation, while the added layer of foam with silver hydrogen zirconium phosphate is designed to keep the wound free of infection for up to but not to exceed seven days of use. This product is available in 5 standard sizes, and can be custom ordered in other dimensions.

Attachment #05.156
Ken Lester of Millennial Medical Equipment, LLC submitted a request that CMS either assign existing code E0117 for use to identify the Millennial Crutch; or modify an existing code or create a new code to describe the unique features of Millennial Crutch and assign it "a reimbursement range that reflects its added value to the user over existing standard crutches". Existing code E0117 reads: "CRUTCH, UNDERARM, ARTICULATING SPRING ASSISTED, EACH". According to the requester, the Millennial Crutch operates the same way traditional crutches do. They are placed slightly below the armpit with the tip touching the ground in front of the user. Grasping the handle the user moves in a forward direction supporting his or her weight on the hands and arms and steps or swings taking the weight off of the involved leg. Millennial

Crutch has a spring shock-absorbing/power assist feature which compresses as the crutch is planted ahead of the user, and as he or she steps through, releases the tension of the spring positively to help him or her propel forward. This requires less energy of the user than it would with conventional crutches. Millennial crutch is adjusted to the height of the user and to proper arm angle and gripping position. The crutch also detaches at the mid-section so that it can be collapsed or folded.

Attachment #05.157
Wayne Urban of LS Products LLC submitted a request to establish a code for a leg sling, trade name: Webb's Leg Sling. According to the requester, Webb's Leg Sling is a lightweight shoulder harness that suspends a patient's injured leg in a flexible position for patients using crutches or walkers. The harness designed to keep weight off of one leg for the purpose of supporting a weak or injured foot or ankle in a physician ordered non-weight bearing circumstance. It functions by transferring the weight of the lower leg to the opposite shoulder using a harness made of durable, high strength, polypropylene webbing. Another similar harness is worn around the injured foot and ankle of the injured limb. An elastic mid-section connects the two harnesses near the hip area. The shoulder harness is adjustable in order to support the injured foot a few inches off the ground. The shoulder harness and shin/ankle cuff are padded for comfort and protection. According to the applicant, existing code A4565 "Slings" does not adequately describe this product, and A4565 " is an old code which describes cloth and canvas arm slings" and payment rates are inadequate to cover manufacturing costs of this product.

Attachment #05.158
Tom Weaver of the American Optometric Association submitted a request to establish a unique code for solid tint and glass color coating. Presently, solid and gradient tints are both described in existing code V2745 ADDITION TO LENS; TINT, ANY COLOR, SOLID, GRADIENT OR EQUAL, EXCLUDES PHOTOCHROMATIC, ANY LENS MATERIAL, PER LENS. The applicant seeks to separate solid tint from other tints and states in this application that "solid tints are less expensive to manufacturer than a gradient tint and usually have a lower reimbursement." According to the requester, solid tint is a treatment that is applied as a coating to a glass or plastic lens or is added to the lens material during the manufacturing process. The tint remains constant throughout the lens. Solid tints reduce light transmission, which improves eye comfort and enhances visual performance. The specific benefits of a tint are its ability to reduce glare, to provide some level of UV protection, to help counteract negative effects of certain lighted environments such as fluorescent lighting in offices. Tints may reduce the effects of certain ocular conditions and enhance the aesthetic appearance of the eyewear.

Attachment #05.159
Anne Sather of Hypoguard submitted a request to establish a code for an express blood glucose monitoring system, NewTeK™. According to the requester, NewTek is a self-contained blood glucose monitoring system with 100 pre-loaded, pre-calibrated test strips

included in the device. The device is disposed of after 100 uses. NewTek reads a patient's blood glucose level with its pre-loaded, pre-calibrated test strips. The user simply pulls a lever to dispense a test strip, places their capillary blood sample on the strip, and waits 15 seconds for test results. Once the blood glucose level is read, the patient ejects the test strip from the meter by pushing the lever backwards. NewTek is used for persons with diabetes to aid in monitoring the effectiveness of diabetes control by quantitatively measuring the glucose in a fresh capillary whole blood sample. The applicant describes this product as a unique self-contained blood glucose monitor and 100 test strips in one device. Therefore, according to the applicant, codes separately describing only the test strip or only the monitor do not adequately describe this product. The applicant acknowledges that this product does not meet Medicare's definition of DME and that for Medicare, A9270 is the appropriate code. The applicant, however, is seeking a code for use by state Medicaid agencies and Private Insurers.

Attachment #05.160
Patty Curoe of Medtronic Diabetes (MiniMed) has submitted a request to establish 3 separate codes to reflect the 3 components of the Guardian® Telemetered Glucose Monitoring System. The applicant suggests the following language for the 3 requested codes: 1) "Sensors; interstitial continuous glucose monitoring system, per sensor"; 2) "transmitter; interstitial continuous glucose monitoring system"; 3) "monitor; interstitial continuous glucose monitoring system". According to the requestor, the Guardian System is a glucose monitoring system that continuously records glucose values measured in interstitial fluids such as those in subcutaneous tissue. The patient inserts a subcutaneous sensor under the skin which records glucose values every ten seconds and transmits results wirelessly to a small external monitor. The monitor is designed to alert the patient when glucose values go above or below the target ranges prescribed by the physician.

Attachment #05.161
John Neet and Geoffrey Hartzler, M.D. of IntraLuminal Therapeutics, Inc. have submitted a request to establish a code for a radio frequency total occlusion crossing system, Trade Name: The Safe-Cross® Radio Frequency Total Occlusion Crossing Wire. According to the requestor, the Safe-Cross Radio Frequency Total Occlusion Crossing Wire is a sterile, single use guide wire with an intelligent optical guidance capacity and controlled radio frequency micro-ablation technology built into the tip. It is used to cross total occlusions in the coronary and peripheral arteries. With an optical fiber embedded into the guide wire, the system is able to provide guidance feedback to the operator through optical coherence reflectometry.

Attachment #05.162
Dan Tradden of Cytyc LP has submitted a request to establish a code for an endometrial ablation system, Trade Name: NovaSure™ Catheter, Ablation, Radio Frequency (RF), Impedence Controlled, Endometrial. According to the requestor, this product applies a

precisely controlled dose of electrical energy to remove the lining of the uterus, or endometrium, in women diagnosed with excessive menstrual bleeding due to benign causes in pre-menopausal women for whom childbearing is complete. CPT code 58563 HYSTEROSCOPY, SURGICAL; WITH ENDOMETRIAL ABLATION (EG, ENDOMETRIAL RESECTION, ELECTROSURGICAL ABLATION, THERMOABLATION) is currently used to describe this procedure. According to the requester, the RVU's associated with CPT 58563 include the cost of the device when the procedure is performed in a physician's office; the APC payment includes the cost of the device when the procedure is performed in the hospital outpatient department. However, the requester claims that the payment assigned to Group 4 of the Medicare ASC Fee Schedule does not include the cost of the device, and is seeking a code and a means of compensating for the device in an ASC.

Attachment #05.163
Darralyn Alexander of MD Anderson Cancer Center submitted a request to establish a code for an anatomical model, trade name: ClearView® Anatomical View. According to the requester, these anatomic models are life-sized diagnostic models that duplicate the bone and/or soft tissues of an individual patient's anatomy in polymer-type materials. The models are produced using digital information gained from the patient's routine diagnostic computer assisted tomography scan (CT scan) obtained from the treating hospital. These models are used to plan for surgery for obliterated skull and facial bones, spinal deformities, and large bone defects and injuries of the hips, legs and arms and etc. Use of anatomical models enable the surgeons to better plan a procedure and evaluate possible surgical options and problems by evaluating a physical duplication of the anatomy before surgery is initiated and an incision is made. It allows physicians to test a number of surgical options, and choose the best technique to achieve the sought after outcome, with more accuracy and to carry it out more effectively and in less time that might be needed without the use of such a diagnostic and evaluative technology. The applicant states that "no CPT code allows reimbursement" for the cost of the model. The requester is seeking a remedy via HCPCS coding.

Attachment #05.164
Deanna Eaves of Hollister submitted a request to revise existing code A4413 OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, FOR USE ON A BARRIER WITH FLANGE (2 PIECE SYSTEM), WITH FILTER, EACH to change the words "with filter" to instead read "with or without filter" to accurately describe drainable high output pouches that do not include a filter. According to the requester, CenterPointLock is a drainable ostomy pouch that allows for increased output. It is transparent and has a capacity greater than 0.75 liters. CenterPointLock is used for people with an ostomy or surgically created opening for removal of bodily waste. This pouch is specifically designed for liquid-type stools that may be more common in an ileostomate or a colostomate who is experiencing diarrhea. It does not have a filter because filters can be easily compromised if allowed to get wet; and it does not have an anti-reflux valve because such valves may become

clogged with stool. CenterPointLock is applied to the body using a connection to a barrier with flange. It is available in three flange sizes.

Attachment #05.165
Jeffrey A. Hameroff, D.D.S. of BHM Laboratories has submitted a request to establish a code for unit dose Stannous Fluoride Concentrate, Trade Name: MedOral Anti-microbial Fluoride Rinse. According to the requestor, MedOral-Anti-Microbial Fluoride Rinse is a two-part 1oz. dose of 0.63% Stannous Fluoride solution. The rinse acts on gram negative biofilm bacteria colonies in the oral cavity, when used three times daily as a preventative. The applicant claims that daily use diminishes oral pathogens associated with a large variety of systemic diseases and that the therapeutic goal of MedOral Fluoride Rinse is to minimize potential negative influences of oral pathogens in conditions such as cardiovascular disease and diabetes as well as pulmonary disease. It is considered an over the counter drug supplied as a unit-dose, self contained packaging design that can be administered by an attending nurse or nurse's aid.

Attachment #05.166
Jeffrey A. Hameroff, D.D.S. of BHM Laboratories has submitted a request to establish a code for MedOral Dry Mouth Treatment, Trade Name: MedOral Dry Mouth Treatment. According to the requestor, MedOral Dry Mouth Treatment is a non-aerosol spray that moistens the oral cavity and helps replenish saliva in the patients with dry mouth symptoms. The product is sprayed in the mouth distributed by the tongue and reapplied, as needed approximately every one to two hours. It is indicated in a broad population of patients, including but not limited to those with medication induced dry mouth, xerostomia, diabetes, cancer treatment patients, and others. It is primarily an oral aid in rewetting the oral mucosa surfaces.

Attachment #05.167
Kirk MacKenzie of Snug Seat has submitted a request to establish 2 codes: 1) pediatric dynamic stander and three way stander, Trade Name: Pediatric Dynamic Stander – Rabbit Mobile Stander (Snug Seat) and 2) Pediatric Three-Way Stander, angle adjustable, permits prone, supine, and vertical standing – Gazelle P/S Standing Frame (Snug Seat). According to the requestor, a pediatric dynamic stander is a device that places a child who cannot stand independently, in an upright or prone position and allows him to self-propel. The stander angle accommodates a range from upright to > 20 degrees prone. It differs from a basic simple standing frame in that the simple standing frame serves one single purpose – upright standing, prone standing, or supine standing, while the pediatric dynamic stander is a standing device that provides the child with independent mobility.

Attachment #05.168
Mary St. Pierre of the National Association for Home Care and Hospice has submitted a request to establish a code for social work services in the home, per visit. Social work

services visits are provided to individuals in their homes for medically necessary care. Home care providers have traditionally billed and been paid for intermittent social work services care on a per visit basis. Existing codes are available to identify social work services visits in 15 minute increments, by the hour and per diem.

Attachment #05.169
Mary St. Pierre of the National Association for Home Care and Hospice has submitted a request to establish a code for occupational therapy, in the home, per visit. According to the requestor, HCPCS codes are available for reporting home health services in 15 minute increments, as required by Medicare, and hourly and per diem as needed for payers who pay these services in these increments. No codes currently exist for "visits".

Attachment #05.170
Mary St. Pierre of the National Association for Home Care and Hospice has submitted a request to establish a code for speech language pathology services, in the home, per visit. According to the requestor, HCPCS codes are available for reporting home health services in 15 minute increments, as required by Medicare, and hourly and per diem as needed for payers who pay these services in these increments. No codes currently exist for "visits".

Attachment #05.171
Mary St. Pierre of the National Association for Home Care and Hospice has submitted a request to establish a code for "nursing, in the home, per visit." According to the requestor, HCPCS codes are available for reporting home health services in 15 minute increments, as required by Medicare, and hourly and per diem as needed for payers who pay these services in these increments. No codes currently exist for "visits".

Attachment #05.172
Mary St. Pierre of the National Association for Home Care and Hospice has submitted a request to establish a code for "physical therapy, in the home, per visit". According to the requestor, HCPCS codes are available for reporting home health services in 15 minute increments, as required by Medicare, and hourly and per diem as needed for payers who pay these services in these increments. No codes currently exist for "visits".

Attachment #05.181
Rebecca Fancher of Protex Medical Products, Inc. submitted a request to establish a code for a limb cover and torso coverings, trade name: Protex Limb Protectors and Body Covers. According to the requester the Protex product line includes limb protectors that are protective coverings for the arms and legs, and two torso coverings, that help pressure the integrity of a wound, dressing, surgery site, cast, vaccine, IV, PICC line, venous procedures, burns, rashes or any other area of concern that needs to be protected from

damaging moisture or other contaminants, especially during a bathing process. These covers fit over and seal off the area of concern to allow the wearer to resume and maintain normal bathing routines or daily activities, using a simple one-step process.

Attachment #05.182
Steve Cooley of Welcon Medical Products submitted a request to establish a code for an enteral irrigation syringe, trade name: Welcon Pillcrusher™ Enteral Irrigation Syringe. According to the requester, the PillCrusher is an "all-in-one" system for the crushing, dissolving, and delivery of soluble solid medications in water. It is designated for use with patients using enteral feeding tubes or who have difficulty swallowing. The solid medication is placed into the syringe and then crushed into a powder form by pressing and rotating the syringe piston against the medication. Sterile water is then drawn into the syringe and the syringe is shaken or agitated to completely dissolve the medication powder. This medicated solution is then injected through the enteral feeding tube or administered orally to deliver the proper medication and dosage amount to the patient.

Attachment #05.183
Eric Dixon of EProducts, Inc. submitted a request to establish a code for a non-invasive drinking apparatus for measuring and managing fluid intake, trade name: DigiStraw. According to the requester, DigiStraw is a non-invasive drinking apparatus for measuring and managing fluid intake. It includes a disposable straw for the user to draw fluid. A flow sensor is attached in-line to the straw for measuring the fluid flow rate. An electronic microprocessor is connected to the flow sensor to convert the flow rate to volume. A display enables the patient to view the total amount of liquid consumed and set threshold amounts. A total amount of fluid can be set as an alarm threshold. DigiStraw is powered by two 3 volt batteries. This device is targeted at managing interdialytic fluids for hemodialysis patients, dehydration management in elderly and cardiac patients. DigiStraw can be mounted on most cups, glasses or cans. As the user sucks on the straw, flow sensor measures the flow of fluid through the straw and micro-controller converts the flow signal to volume and adds the measured volume flow to a stored volume, and displays the cumulative volume on display. When turned off, the total volume is stored in the micro-controller until reset.